

US3822015 (Prod: Tryon Medical Partners, PLLC)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:50:28

All time stamps listed in this document are displayed in GMT

US3822015

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

Participant ID

US3822015

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

US3822015

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3822015

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 19:09:18

Generated On: 10 Jun 2021 09:50:28

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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 19:09:18

Generated On: 10 Jun 2021 09:50:28

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 <input checked="" type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3822015

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 19:09:18

Generated On: 10 Jun 2021 09:50:28

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Condition	HYPOGONADISM
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3822015

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

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

US3822015

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

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

US3822015

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

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

US3822015

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Condition	RESTLESS LEG SYNDROME
Start date (dd MMM yyyy)	UN NOV 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3822015

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Condition	PERIPHERAL NERVE DISEASE
Start date (dd MMM yyyy)	UN NOV 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Condition	ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Condition	HYPERCOAGULABILITY STATE
Start date (dd MMM yyyy)	27 DEC 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Condition	TRICUSPID VALVE REGURGITATION
Start date (dd MMM yyyy)	03 DEC 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Condition	MITRAL VALVE REGURGITATION
Start date (dd MMM yyyy)	03 DEC 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Condition	AORTIC VALVE REGURGITATION
Start date (dd MMM yyyy)	27 DEC 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3822015

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Condition	PULMONIC VALVE REGURGITATION
Start date (dd MMM yyyy)	01 APR 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Condition	BIOTRINK PACEMAKER INSERTION
Start date (dd MMM yyyy)	01 APR 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Condition	SINUS NODE DYSFUNCTION
Start date (dd MMM yyyy)	01 APR 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Condition	CHRONOTROPIC INCOMPETENCE
Start date (dd MMM yyyy)	01 APR 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Condition	ALLERGIC RHINITIS
Start date (dd MMM yyyy)	16 NOV 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3822015

Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Condition	BENIGN PROSTAIC HYPERPLASIA
Start date (dd MMM yyyy)	27 NOV 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3822015

Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

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

US3822015

Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Condition	SENILE PURPURA LEFT ARM
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3822015

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
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
Height (xxx.x)	68 in
Weight (xxx.x)	189.6 lb
BMI (xxx.x)	28.88886 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3822015

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

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.

US3822015

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 19:09:19

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

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 ☒

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	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 <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	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)

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	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 <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	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

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

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.

US3822015

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

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

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

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

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Collection date (dd MMM yyyy)			05 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	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

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

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

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

Yes <input type="checkbox"/>	
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: 10 Jun 2021 09:50:28

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 ☒

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US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:28

Yes <input type="checkbox"/>	
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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

Yes <input type="checkbox"/>	
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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

Yes <input type="checkbox"/>	
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: 10 Jun 2021 09:50:28

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 ☒

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EAB) (1725)

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:28

Yes <input type="checkbox"/>	
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: 10 Jun 2021 09:50:28

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:28

Yes <input type="checkbox"/>	
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

Data signed: (b) (4) 12 Feb 2021 19:09:18

Generated On: 10 Jun 2021 09:50:28

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

Data signed: (b) (4) 12 Feb 2021 19:09:18

Generated On: 10 Jun 2021 09:50:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822015

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:09:18

Generated On: 10 Jun 2021 09:50:28

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

Data signed: (b) (4) 12 Feb 2021 19:09:18

Generated On: 10 Jun 2021 09:50:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:09:18

Generated On: 10 Jun 2021 09:50:28

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

Data signed: (b) (4) 12 Feb 2021 19:09:18

Generated On: 10 Jun 2021 09:50:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 SEP 2020
Time of assessment (00:00-23:59)	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 <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	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)

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 SEP 2020
Time of assessment (00:00-23:59)	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 <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

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

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

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

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

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

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

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

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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: 10 Jun 2021 09:50:28

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

Yes <input type="checkbox"/>	
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: 10 Jun 2021 09:50:28

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 ☒

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EAB) (1725)

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US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:28

Yes <input type="checkbox"/>	
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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

Yes <input type="checkbox"/>	
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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

Yes <input type="checkbox"/>	
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: 10 Jun 2021 09:50:28

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 ☒

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EAB) (1725)

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US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:28

Yes <input type="checkbox"/>	
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: 10 Jun 2021 09:50:28

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 ☒

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EAB) (1725)

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US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:28

Yes <input type="checkbox"/>	
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

Data signed: (b) (4) 12 Feb 2021 19:09:18

Generated On: 10 Jun 2021 09:50:28

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

Data signed: (b) (4) 12 Feb 2021 19:09:18

Generated On: 10 Jun 2021 09:50:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822015

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:09:18

Generated On: 10 Jun 2021 09:50:28

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

Data signed: (b) (4) 12 Feb 2021 19:09:18

Generated On: 10 Jun 2021 09:50:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822015

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:09:18

Generated On: 10 Jun 2021 09:50:28

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

Data signed: (b) (4) 12 Feb 2021 19:09:18

Generated On: 10 Jun 2021 09:50:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822015

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3822015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

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

US3822015

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

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

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 OCT 2020
Collection time (00:00-23:59)	11:51 (24 HR)
Collection date and time (derived)	1 OCT 2020 11:51

US3822015

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:09:19

Generated On: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 NOV 2020 06:14:31

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: 10 Jun 2021 09:50:28

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 DEC 2020 07:32:55

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: 10 Jun 2021 09:50:28

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 DEC 2020 07:39:56

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: 10 Jun 2021 09:50:28

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 DEC 2020 07:02:33

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: 10 Jun 2021 09:50:28

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 DEC 2020 08:41:58

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: 10 Jun 2021 09:50:28

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 JAN 2021 07:26:06

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: 10 Jun 2021 09:50:28

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 07:38:28

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: 10 Jun 2021 09:50:28

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 06:12:53

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: 10 Jun 2021 09:50:28

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 06:55:59

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: 10 Jun 2021 09:50:28

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

Date and time of submission

29 JAN 2021 07:22:53

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: 10 Jun 2021 09:50:28

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 FEB 2021 07:10:05

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: 10 Jun 2021 09:50:28

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 FEB 2021 06:25:09

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: 10 Jun 2021 09:50:28

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 07:50:20
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: 10 Jun 2021 09:50:28

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 FEB 2021 07:16:11

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: 10 Jun 2021 09:50:28

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 06:54:09

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: 10 Jun 2021 09:50:28

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 MAR 2021 06:50:49

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: 10 Jun 2021 09:50:28

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 07:11:57

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: 10 Jun 2021 09:50:28

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 06:53:39

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: 10 Jun 2021 09:50:28

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 07:44:22

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: 10 Jun 2021 09:50:28

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 06:33:57

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: 10 Jun 2021 09:50:28

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 07:04:04

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: 10 Jun 2021 09:50:28

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

Date and time of submission

23 APR 2021 06:47:12

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: 10 Jun 2021 09:50:28

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 06:55:48

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: 10 Jun 2021 09:50:28

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

07 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: 10 Jun 2021 09:50:28

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

14 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: 10 Jun 2021 09:50:28

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

21 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

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: 10 Jun 2021 09:50:28

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

04 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

11 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: 10 Jun 2021 09:50:28

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

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: 10 Jun 2021 09:50:28

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 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: 10 Jun 2021 09:50:28

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

02 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: 10 Jun 2021 09:50:28

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

09 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: 10 Jun 2021 09:50:28

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

23 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

06 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: 10 Jun 2021 09:50:28

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

Patient Cloud Open Date & Time	13 AUG 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

Patient Cloud Open Date & Time	20 AUG 2021 00:01
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Patient Cloud Close Date & Time	24 AUG 2021 23:59
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US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

03 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

10 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: 10 Jun 2021 09:50:28

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

17 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

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: 10 Jun 2021 09:50:28

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

Patient Cloud Open Date & Time	01 OCT 2021 00:01
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Patient Cloud Close Date & Time	05 OCT 2021 23:59
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US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

08 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 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: 10 Jun 2021 09:50:28

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

29 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: 10 Jun 2021 09:50:28

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

05 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

Patient Cloud Open Date & Time	12 NOV 2021 00:01
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Patient Cloud Close Date & Time	16 NOV 2021 23:59
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US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

19 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

26 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: 10 Jun 2021 09:50:28

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

03 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

17 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

Patient Cloud Open Date & Time	24 DEC 2021 00:01
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Patient Cloud Close Date & Time	28 DEC 2021 23:59
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US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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°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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

07 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: 10 Jun 2021 09:50:28

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

14 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

04 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

11 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

25 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

04 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

11 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: 10 Jun 2021 09:50:28

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°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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

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: 10 Jun 2021 09:50:28

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

25 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

01 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: 10 Jun 2021 09:50:28

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 APR 2022 00:01
Patient Cloud Close Date & Time	19 APR 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 APR 2022 00:01
Patient Cloud Close Date & Time	26 APR 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

29 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

06 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: 10 Jun 2021 09:50:28

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 MAY 2022 00:01
Patient Cloud Close Date & Time	17 MAY 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

20 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUN 2022 00:01
Patient Cloud Close Date & Time	14 JUN 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

Patient Cloud Open Date & Time	15 JUL 2022 00:01
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Patient Cloud Close Date & Time	19 JUL 2022 23:59
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US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

22 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

29 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: 10 Jun 2021 09:50:28

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

05 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: 10 Jun 2021 09:50:28

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

Patient Cloud Open Date & Time	12 AUG 2022 00:01
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Patient Cloud Close Date & Time	16 AUG 2022 23:59
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US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

19 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

Patient Cloud Open Date & Time	26 AUG 2022 00:01
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Patient Cloud Close Date & Time	30 AUG 2022 23:59
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US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

02 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: 10 Jun 2021 09:50:28

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

09 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

16 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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

23 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: 10 Jun 2021 09:50:28

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 10 Jun 2021 09:50:28

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3822015

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:50:28

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		05 MAR 2021 06:54:46

US3822015

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:05:29

Generated On: 10 Jun 2021 09:50:28

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

Data signed: (b) (4) 05 Mar 2021 15:05:29

Generated On: 10 Jun 2021 09:50:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822015

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:00:26

Generated On: 10 Jun 2021 09:50:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822015

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:00:26

Generated On: 10 Jun 2021 09:50:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822015

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:00:26

Generated On: 10 Jun 2021 09:50:28

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 DEC 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 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:00:26

Generated On: 10 Jun 2021 09:50:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822015

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:00:26

Generated On: 10 Jun 2021 09:50:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822015

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:00:26

Generated On: 10 Jun 2021 09:50:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822015

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:00:26

Generated On: 10 Jun 2021 09:50:28

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

Visit date (dd MMM yyyy)	15 MAR 2021
--------------------------	-------------

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

Folder OID	VISIT4
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US3822015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:00:26

Generated On: 10 Jun 2021 09:50:28

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3822015

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:00:26

Generated On: 10 Jun 2021 09:50:28

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 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:00:26

Generated On: 10 Jun 2021 09:50:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 MAR 2021
Collection time (00:00-23:59)	11:45 (24 HR)
Collection date and time (derived)	15 MAR 2021 11:45

US3822015

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:00:26

Generated On: 10 Jun 2021 09:50:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822015

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 11 Apr 2021 23:55:49

Generated On: 10 Jun 2021 09:50:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 APR 2021

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 239 (1)

Form: Continuing

Data signed: (b) (4) 11 Apr 2021 23:55:49

Generated On: 10 Jun 2021 09:50:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822015

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

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 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3822015

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:50:28

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

US3822015

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:50:28

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3822015

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

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

Visit date (dd MMM yyyy)	11 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3822015

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 06:15:38

Generated On: 10 Jun 2021 09:50:28

Date of updated informed consent (<i>dd MMM yyyy</i>)	11 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	10 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3822015

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

Height	68 in
Weight	185.2 lb
BMI (xxx.x)	28.21844

US3822015

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

Height	68 in
Weight	185.2 lb
BMI (xxx.x)	28.21844
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 JAN 2021
Time of assessment (00:00-23:59)	14:53 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 14:53
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3822015

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

Height	68 in
Weight	185.2 lb
BMI (xxx.x)	28.21844
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 JAN 2021
Time of assessment (00:00-23:59)	16:00 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 16:00
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3822015

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

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 JAN 2021

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

US3822015

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

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 11 JAN 2021

What was the treatment time? (00:00-23:59) 15:25 (24 HR)

Treatment Date and Time (derived) 11 JAN 2021 15:25

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: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 JAN 2021

Collection time (00:00-23:59)

14:58 (24 HR)

Collection date and time (derived)

11 JAN 2021 14:58

US3822015

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

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

Collection date (dd MMM yyyy)	11 JAN 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	15:15
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Collection Date and Time (derived)	11 JAN 2021 15:15
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US3822015

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

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822015

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:00:26

Generated On: 10 Jun 2021 09:50:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

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 OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:00:26

Generated On: 10 Jun 2021 09:50:28

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

US3822015

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 FEB 2021
Time of assessment (00:00-23:59)	13:10 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 13:10
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 FEB 2021
Time of assessment (00:00-23:59)	14:00 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 14:00
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3822015

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

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: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 08 FEB 2021

What was the treatment time? (00:00-23:59) 13:26 (24 HR)

Treatment Date and Time (derived) 08 FEB 2021 13:26

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: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822015

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:00:26

Generated On: 10 Jun 2021 09:50:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822015

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:00:26

Generated On: 10 Jun 2021 09:50:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822015

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3822015

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3822015

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

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: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	15 MAR 2021
Collection time (<i>00:00-23:59</i>)	11:45 (24 HR)
Collection date and time (derived)	15 MAR 2021 11:45

US3822015

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 18:45:01

Generated On: 10 Jun 2021 09:50:28

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)

Data signed: (b) (4) 26 Mar 2021 17:47:08

Generated On: 10 Jun 2021 09:50:28

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

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US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Mar 2021 17:47:08

Generated On: 10 Jun 2021 09:50:28

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

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Mar 2021 17:47:08

Generated On: 10 Jun 2021 09:50:28

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)

Data signed: (b) (4) 26 Mar 2021 17:47:08

Generated On: 10 Jun 2021 09:50:28

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)

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Mar 2021 17:47:08

Generated On: 10 Jun 2021 09:50:28

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

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Mar 2021 17:47:08

Generated On: 10 Jun 2021 09:50:28

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Mar 2021 17:47:08

Generated On: 10 Jun 2021 09:50:28

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Mar 2021 17:47:08

Generated On: 10 Jun 2021 09:50:28

AEID

Adverse event

PHRENIC NERVE DAMAGE

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)

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Mar 2021 17:47:08

Generated On: 10 Jun 2021 09:50:28

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

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Mar 2021 17:47:08

Generated On: 10 Jun 2021 09:50:28

PATIENT SUSTAINED DAMAGE
TO THE PHRENIC NERVE
DURING CARDIAC ABLATION
AND REQUIRED HOSPITAL
STAY FROM 09SEP2020 TO
13SEP2020. PATIENTS
METOPROLOL DOSE WAS
CHANGED. SAE, AE, AND CON
MED HISTORY HAS ALREADY
BEEN UPDATED.

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: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 26 Mar 2021 17:47:08

Generated On: 10 Jun 2021 09:50:28

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 26 Mar 2021 17:47:08

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

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

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)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

Name of Medication METROPROLOL SUCCINATE ER

Prophylaxis Yes ☐
No ☒

Indication PAROXYSMAL ATRIAL
FIBRILLATION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

Name of Medication TYLENOL PM

Prophylaxis Yes ☐
No ☒

Indication OBSTRUCTIVE SLEEP APNEA

Dose per administration 500/25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

Name of Medication METOPROLOL SUCCINATE

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication BILATERAL EDEMA,
EXTREMITIES (ARMS/LEGS)

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 ☐

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EAB) (1725)

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US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		12 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

Name of Medication AMIODARONE

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication HEART FAILURE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 02 Apr 2021 20:00:24

Generated On: 10 Jun 2021 09:50:28

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

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	Adverse Event	
10 SEP 2020	ECHOCARDIOGRAM	Adverse Event	
11 SEP 2020	INCENTIVE SPIROMETER	Other	PROPHYLAXIS
29 JAN 2021	CARDIOVERSION	Adverse Event	

US3822015

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:50:28

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:50:28

Date of study discontinuation/completion (<i>dd MMM yyyy</i>)	
Reason for discontinuation	AE (specify) <input type="checkbox"/>
	SAE (specify) <input type="checkbox"/>
	Complete <input type="checkbox"/>
	Death <input type="checkbox"/>
	Lost To Follow-up <input type="checkbox"/>
	Physician decision (specify) <input type="checkbox"/>
	Pregnancy <input type="checkbox"/>
	Protocol deviation (specify) <input type="checkbox"/>
	Study Terminated By Sponsor <input type="checkbox"/>
	Withdrawal of consent by participant (specify) <input type="checkbox"/>
	Other <input type="checkbox"/>
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	
If reason for discontinuation is Death, main cause of death	Adverse event <input type="checkbox"/>
	Unknown <input type="checkbox"/>
	Other <input type="checkbox"/>
If main cause of death is Other, specify	
Date of death (<i>dd MMM yyyy</i>)	
Was autopsy performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
	Unknown <input type="checkbox"/>

US3822015

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

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

SAEID	USA-US126-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	12

US3822015

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

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

SAEID	USA-US126-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	12
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)

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

SAEID	USA-US126-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	12
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)

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

SAEID	USA-US126-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	12
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)

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

SAEID	USA-US126-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	12
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)

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

SAEID	USA-US126-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	12
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)

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

SAEID	USA-US126-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	12
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)

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

SAEID	USA-US126-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	12
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)

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

SAEID	USA-US126-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	12
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

US3822015

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

Form: Safety Report Form (9)

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

SAEID	USA-US126-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	12
Date of submission (Pre-filled from custom function)	02/FEB/2021 12:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3822015

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

Form: Safety Report Form (10)

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

SAEID	USA-US126-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	12
Date of submission (Pre-filled from custom function)	08/FEB/2021 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

US3822015

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

Form: Safety Report Form (11)

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

SAEID	USA-US126-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	12
Date of submission (Pre-filled from custom function)	16/MAR/2021 12:30
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3822015

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

Form: Safety Report Form (12)

Data signed: (b) (4) 02 Apr 2021 20:00:25

Generated On: 10 Jun 2021 09:50:28

SAEID	USA-US126-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	12
Date of submission (Pre-filled from custom function)	24/MAR/2021 13:30
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3822015 (Prod: Tryon Medical Partners, PLLC)

US3822015

Form: Participant Creation

Generated On: 10 Jun 2021 09:50:28

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User entered 'SCRN'	System	05 Aug 2020 17:08:34

US3822015

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:28

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:07:59
User entered '83'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:08:53

US3822015

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:28

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User entered 'YEARS'	System	05 Aug 2020 17:08:53

US3822015

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:28

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User entered '83'	System	05 Aug 2020 17:09:10

US3822015

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:28

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:07:59
User entered 'Male (M)'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:08:53

US3822015

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:28

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:07:59
User entered 'I'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:08:53

US3822015

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:28

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:07:59
User entered '0'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:08:53

US3822015

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:28

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:07:59
User entered '0'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:08:53

US3822015

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:28

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:07:59
User entered '0'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:08:53

US3822015

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:28

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:07:59
User entered '0'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:08:53

US3822015

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:28

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:07:59
User entered '0'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:08:53

US3822015

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:28

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:07:59
User entered '0'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:08:53

US3822015

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:28

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:07:59
User entered '0'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:08:53

US3822015

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:50:28

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:08:30
User entered '05 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:09:10

US3822015

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User entered 'Aug 2020'	System	05 Aug 2020 17:09:10

US3822015

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User entered '2020'	System	05 Aug 2020 17:09:10

US3822015

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:50:28

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User entered 'I'	System	05 Aug 2020 17:09:16

US3822015

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
User closed query 'If applicable, please add Purpurpa on left arm and skin lesion on right arm as noted at Screening Physical.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:17:01
Query 'If applicable, please add Purpurpa on left arm and skin lesion on right arm as noted at Screening Physical.' answered with 'added' (Site from CRA).	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:09:03
User opened query 'If applicable, please add Purpurpa 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) (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) (b) (4)	16 Aug 2020 13:20:05

US3822015

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:50:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
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)	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)	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)	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)	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)	16 Aug 2020 13:21:41

US3822015

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:21:41

US3822015

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:50:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:21:41

US3822015

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:50:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:21:41

US3822015

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:21:41

US3822015

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:50:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:21:41

US3822015

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:22:30

US3822015

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:50:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:22:30

US3822015

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:50:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:22:30

US3822015

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:22:30

US3822015

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:50:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:22:30

US3822015

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	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 16:17:38
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, HLGT: 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.	Coder Import (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

US3822015

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:22:58

US3822015

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:50:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:22:58

US3822015

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:50:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:22:58

US3822015

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:22:58

US3822015

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:50:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:22:58

US3822015

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
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)	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 16:17:38
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)	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)	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)	16 Aug 2020 13:24:58

US3822015

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:24:58

US3822015

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:50:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:24:58

US3822015

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:50:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:24:58

US3822015

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:24:58

US3822015

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:50:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:24:58

US3822015

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
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)	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)	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)	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)	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)	16 Aug 2020 13:25:34

US3822015

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:25:34

US3822015

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:50:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:25:34

US3822015

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:50:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:25:34

US3822015

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:25:34

US3822015

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:50:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:25:34

US3822015

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
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)	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)	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)	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)	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)	16 Aug 2020 13:26:05

US3822015

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:26:05

US3822015

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:50:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:26:05

US3822015

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:50:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:26:05

US3822015

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:26:05

US3822015

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:50:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:26:05

US3822015

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4)	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)	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 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.	Krishna Shah (b) (4)	28 Sep 2020 21:25:04
' answered with 'updated ' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(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

US3822015

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:50:28

[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)	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)	16 Aug 2020 13:28:14
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:26:38

US3822015

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:50:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:26:38

US3822015

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:50:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:26:38

US3822015

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:26:38

US3822015

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:50:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:26:38

US3822015

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
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)	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 16:17:39
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 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.	Krishna Shah (b) (4)	28 Sep 2020 21:25:15
' answered with 'updated ' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(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)	16 Aug 2020 13:29:15

US3822015

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:28

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	16 Aug 2020 13:29:15
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	16 Aug 2020 13:27:51
User entered 'Atrial Fibrillation'	Kelly Woodell (b) (4)	16 Aug 2020 13:27:17
	(b) (4)	

US3822015

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:27:17

US3822015

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:27:17

US3822015

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:27:17

US3822015

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:27:17

US3822015

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:27:17

US3822015

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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

US3822015

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
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.	(b) (4) Coder Import (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)	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)	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)	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)	16 Aug 2020 13:27:43

US3822015

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:27:43

US3822015

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:50:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:27:43

US3822015

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:50:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:27:43

US3822015

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:27:43

US3822015

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:50:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	16 Aug 2020 13:27:43

US3822015

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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

US3822015

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
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

US3822015

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	07 Sep 2020 21:44:19

US3822015

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:50:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	07 Sep 2020 21:44:19

US3822015

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:50:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	07 Sep 2020 21:44:19

US3822015

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	07 Sep 2020 21:44:19

US3822015

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:50:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	07 Sep 2020 21:44:19

US3822015

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
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.	(b) (4) Coder Import (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)	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)	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 'Tricuspid valve regurgitation'	Kelly Woodell (b) (4)	07 Sep 2020 21:45:13

US3822015

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	07 Sep 2020 21:45:13

US3822015

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:50:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	07 Sep 2020 21:45:13

US3822015

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:50:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	07 Sep 2020 21:45:13

US3822015

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	07 Sep 2020 21:45:13

US3822015

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:50:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	07 Sep 2020 21:45:13

US3822015

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
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.	(b) (4)	
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	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:33:24
Data point term sent to Coder	System	05 Nov 2020 16:17:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:15:30
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.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4), (b) (6)	
Data point term sent to Coder	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered 'Mitral valve regurgitation'	(b) (4), (b) (6)	
	Coder Import (b) (4)	07 Sep 2020 21:46:33
	(b) (4)	
	Coder Import (b) (4)	07 Sep 2020 21:46:33
	(b) (4)	
	System	07 Sep 2020 21:45:52
	Kelly Woodell (b) (4)	07 Sep 2020 21:45:30
	(b) (4)	

US3822015

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	07 Sep 2020 21:45:30

US3822015

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:50:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	07 Sep 2020 21:45:30

US3822015

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:50:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	07 Sep 2020 21:45:30

US3822015

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	07 Sep 2020 21:45:30

US3822015

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:50:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	07 Sep 2020 21:45:30

US3822015

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
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: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	07 Sep 2020 21:45:44

US3822015

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:50:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	07 Sep 2020 21:45:44

US3822015

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:50:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	07 Sep 2020 21:45:44

US3822015

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	07 Sep 2020 21:45:44

US3822015

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:50:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	07 Sep 2020 21:45:44

US3822015

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
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.	(b) (4) 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 16:15:32
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)	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)	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)	07 Sep 2020 21:46:08

US3822015

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	07 Sep 2020 21:46:08

US3822015

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:50:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	07 Sep 2020 21:46:08

US3822015

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:50:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	07 Sep 2020 21:46:08

US3822015

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	07 Sep 2020 21:46:08

US3822015

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:50:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	07 Sep 2020 21:46:08

US3822015

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
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)	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)	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)	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)	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)	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)	22 Oct 2020 18:16:58

US3822015

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	22 Oct 2020 18:16:58

US3822015

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:50:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	22 Oct 2020 18:16:58

US3822015

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:50:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	22 Oct 2020 18:16:58

US3822015

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	22 Oct 2020 18:16:58

US3822015

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:50:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	22 Oct 2020 18:16:58

US3822015

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
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: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
User closed query 'Per CRIO Start Date is 06FEB2019. Please review and reconcile as applicable.' (Site from CRA).	(b) (4) (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) (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) (b) (4)	22 Oct 2020 18:17:35

US3822015

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:50:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	22 Oct 2020 18:17:35

US3822015

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:50:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	22 Oct 2020 18:17:35

US3822015

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	22 Oct 2020 18:17:35

US3822015

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:50:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	22 Oct 2020 18:17:35

US3822015

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
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) (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) (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) (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 16:17:41
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) (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) (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) (b) (4)	22 Oct 2020 18:19:22

US3822015

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	22 Oct 2020 18:19:22

US3822015

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:50:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	22 Oct 2020 18:19:22

US3822015

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:50:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	22 Oct 2020 18:19:22

US3822015

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	22 Oct 2020 18:19:22

US3822015

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:50:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	22 Oct 2020 18:19:22

US3822015

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
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: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	05 Nov 2020 00:35:26

US3822015

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:50:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	05 Nov 2020 00:35:26

US3822015

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	05 Nov 2020 00:35:26

US3822015

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:50:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	05 Nov 2020 00:35:26

US3822015

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
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)	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 16:15:33
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)	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)	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)	05 Nov 2020 00:37:45

US3822015

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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) (b) (4)	06 Nov 2020 22:48:19
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 22:48:14
User entered '27 Nov 2018' reason for change: Data Entry Error	Krishna Shah (b) (4) (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) (b) (4)	05 Nov 2020 00:37:45

US3822015

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:50:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	05 Nov 2020 00:37:45

US3822015

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:50:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	05 Nov 2020 00:37:45

US3822015

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	05 Nov 2020 00:37:45

US3822015

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:50:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	05 Nov 2020 00:37:45

US3822015

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
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.	(b) (4) 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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	05 Nov 2020 01:20:19

US3822015

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:50:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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 'I'	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:20:19

US3822015

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:50:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	05 Nov 2020 01:20:19

US3822015

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	05 Nov 2020 01:20:19

US3822015

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:50:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint activated with code reason code Data required.	(b) (4) (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) (b) (4)	05 Nov 2020 01:20:19

US3822015

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
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)	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
DataPoint Verified.	(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)	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)	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)	05 Nov 2020 01:19:39

US3822015

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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 'I'	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:19:39

US3822015

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:50:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User entered '05 Aug 2020 12:40'	System	16 Aug 2020 13:28:41

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
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: 10 Jun 2021 09:50:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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 change Data Entry Error	(b) (4) Kelly Woodell (b) (4)	16 Sep 2020 22:49:17
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

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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 change Data Entry Error	(b) (4) Kelly Woodell (b) (4)	16 Sep 2020 22:49:17
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

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User entered 'bpm'	System	16 Aug 2020 13:28:41

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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 change Data Entry Error	(b) (4) Kelly Woodell (b) (4)	16 Sep 2020 22:49:17
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

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User entered 'breaths/min'	System	16 Aug 2020 13:28:41

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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 change Data Entry Error	(b) (4) Kelly Woodell (b) (4)	16 Sep 2020 22:49:17
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

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User entered 'mmHg'	System	16 Aug 2020 13:28:41

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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 change Data Entry Error	(b) (4) Kelly Woodell (b) (4)	16 Sep 2020 22:49:17
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

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User entered 'mmHg'	System	16 Aug 2020 13:28:41

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 10:17:57

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 10:17:57

US3822015

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (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).	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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
User entered '0'	Kelly Woodell (b) (4)	16 Aug 2020 13:29:29

US3822015

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:28

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:29:48
User entered 'I'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:29:29

US3822015

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
User entered '0'	Kelly Woodell (b) (4)	16 Aug 2020 13:29:29

US3822015

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:28

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:29:56
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:09:53

US3822015

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:50:28

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:29:56
User entered '05 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:09:53

US3822015

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'VISIT1'	System	05 Aug 2020 17:09:53

US3822015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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) Krishna Shah (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: 10 Jun 2021 09:50:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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) Krishna Shah (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: 10 Jun 2021 09:50:28

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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) Krishna Shah (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: 10 Jun 2021 09:50:28

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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) Krishna Shah (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: 10 Jun 2021 09:50:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
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: 10 Jun 2021 09:50:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
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: 10 Jun 2021 09:50:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'bpm'	System	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'breaths/min'	System	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'mmHg'	System	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'mmHg'	System	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:50:28

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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) Krishna Shah (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: 10 Jun 2021 09:50:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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) Krishna Shah (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: 10 Jun 2021 09:50:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
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: 10 Jun 2021 09:50:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
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: 10 Jun 2021 09:50:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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
User entered '98.9' F reason for change: Data Entry Error	(b) (4) Kelly Woodell (b) (4)	17 Sep 2020 00:28:39
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:34:05
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) (b) (4)	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'bpm'	System	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'breaths/min'	System	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'mmHg'	System	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'mmHg'	System	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:34:53
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:11:43

US3822015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'MRNA-1273 OR PLACEBO'	System	05 Aug 2020 17:11:43

US3822015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered '05 Aug 2020 13:05'	System	05 Aug 2020 17:11:43

US3822015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
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: 10 Jun 2021 09:50:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'INTRAMUSCULAR'	System	05 Aug 2020 17:11:43

US3822015

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
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: 10 Jun 2021 09:50:28

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
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: 10 Jun 2021 09:50:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:35:33
User entered 'Yes (Y)'	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: 10 Jun 2021 09:50:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
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: 10 Jun 2021 09:50:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
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: 10 Jun 2021 09:50:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:35:33
User entered 'No (N)'	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: 10 Jun 2021 09:50:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered empty.	System	16 Aug 2020 13:34:11

US3822015

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'I'	System	16 Aug 2020 13:34:16

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'Yes (Y)'	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: 10 Jun 2021 09:50:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '98.8'	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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'Yes (Y)'	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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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 '0'	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: 10 Jun 2021 09:50:28

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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.'	Kelly Woodell (b) (4)	26 Aug 2020 01:37:44
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 '1'	System	05 Aug 2020 17:35:26

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '05 Aug 2020 13:35'	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: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'Yes (Y)'	System	06 Aug 2020 11:20:12
	System	06 Aug 2020 11:20:12

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '97.1'	System	06 Aug 2020 11:20:12
	System	06 Aug 2020 11:20:12

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	06 Aug 2020 11:20:12
	System	06 Aug 2020 11:20:12

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '06 Aug 2020 07:20'	System	06 Aug 2020 11:20:12
	System	06 Aug 2020 11:20:12

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'Yes (Y)'	System	07 Aug 2020 10:32:52
	System	07 Aug 2020 10:32:52

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '97.2'	System	07 Aug 2020 10:32:52
	System	07 Aug 2020 10:32:52

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	07 Aug 2020 10:32:52
	System	07 Aug 2020 10:32:52

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '07 Aug 2020 06:32'	System	07 Aug 2020 10:32:52
	System	07 Aug 2020 10:32:52

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'Yes (Y)'	System	07 Aug 2020 16:53:25
	System	07 Aug 2020 16:53:25

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '97.1'	System	07 Aug 2020 16:53:25
	System	07 Aug 2020 16:53:25

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '07 Aug 2020 12:53'	System	07 Aug 2020 16:53:25
	System	07 Aug 2020 16:53:25

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '97.6'	System	09 Aug 2020 01:55:38
	System	09 Aug 2020 01:55:38

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '08 Aug 2020 21:55'	System	09 Aug 2020 01:55:38
	System	09 Aug 2020 01:55:38

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'Yes (Y)'	System	10 Aug 2020 02:10:25
	System	10 Aug 2020 02:10:25

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '97.5'	System	10 Aug 2020 02:10:25
	System	10 Aug 2020 02:10:25

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	10 Aug 2020 02:10:25
	System	10 Aug 2020 02:10:25

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '09 Aug 2020 22:10'	System	10 Aug 2020 02:10:25
	System	10 Aug 2020 02:10:25

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'Yes (Y)'	System	11 Aug 2020 02:10:16
	System	11 Aug 2020 02:10:16

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '96.8'	System	11 Aug 2020 02:10:16
	System	11 Aug 2020 02:10:16

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'Yes (Y)'	System	12 Aug 2020 02:04:33
	System	12 Aug 2020 02:04:33

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '97.0'	System	12 Aug 2020 02:04:33
	System	12 Aug 2020 02:04:33

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	12 Aug 2020 02:04:33
	System	12 Aug 2020 02:04:33

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '11 Aug 2020 22:04'	System	12 Aug 2020 02:04:33
	System	12 Aug 2020 02:04:33

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '05 Aug 2020 13:32'	System	05 Aug 2020 17:33:01
	System	05 Aug 2020 17:33:01

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (1)'	System	06 Aug 2020 11:21:50
	System	06 Aug 2020 11:21:50

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	06 Aug 2020 11:21:50
	System	06 Aug 2020 11:21:50

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	06 Aug 2020 11:21:50
	System	06 Aug 2020 11:21:50

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (1)'	System	06 Aug 2020 11:21:50
	System	06 Aug 2020 11:21:50

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '06 Aug 2020 07:21'	System	06 Aug 2020 11:21:50
	System	06 Aug 2020 11:21:50

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (1)'	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: 10 Jun 2021 09:50:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	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: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (1)'	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: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '07 Aug 2020 12:54'	System	07 Aug 2020 16:54:29
	System	07 Aug 2020 16:54:29

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' 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: 10 Jun 2021 09:50:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	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: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '08 Aug 2020 21:56'	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: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (1)'	System	10 Aug 2020 02:11:29
	System	10 Aug 2020 02:11:29

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	10 Aug 2020 02:11:29
	System	10 Aug 2020 02:11:29

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	10 Aug 2020 02:11:29
	System	10 Aug 2020 02:11:29

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (1)'	System	10 Aug 2020 02:11:29
	System	10 Aug 2020 02:11:29

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '09 Aug 2020 22:11'	System	10 Aug 2020 02:11:29
	System	10 Aug 2020 02:11:29

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (1)'	System	11 Aug 2020 02:11:19
	System	11 Aug 2020 02:11:19

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	11 Aug 2020 02:11:19
	System	11 Aug 2020 02:11:19

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	11 Aug 2020 02:11:19
	System	11 Aug 2020 02:11:19

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (1)'	System	11 Aug 2020 02:11:19
	System	11 Aug 2020 02:11:19

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '10 Aug 2020 22:11'	System	11 Aug 2020 02:11:19
	System	11 Aug 2020 02:11:19

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (1)'	System	12 Aug 2020 02:06:17
	System	12 Aug 2020 02:06:17

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	12 Aug 2020 02:06:17
	System	12 Aug 2020 02:06:17

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	12 Aug 2020 02:06:17
	System	12 Aug 2020 02:06:17

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (1)'	System	12 Aug 2020 02:06:17
	System	12 Aug 2020 02:06:17

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	05 Aug 2020 17:38:45
	System	05 Aug 2020 17:38:45

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	05 Aug 2020 17:38:45
	System	05 Aug 2020 17:38:45

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	05 Aug 2020 17:38:45
	System	05 Aug 2020 17:38:45

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	05 Aug 2020 17:38:45
	System	05 Aug 2020 17:38:45

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	05 Aug 2020 17:38:45
	System	05 Aug 2020 17:38:45

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	05 Aug 2020 17:38:45
	System	05 Aug 2020 17:38:45

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '05 Aug 2020 13:38'	System	05 Aug 2020 17:38:45
	System	05 Aug 2020 17:38:45

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	06 Aug 2020 11:22:42
	System	06 Aug 2020 11:22:42

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	06 Aug 2020 11:22:42
	System	06 Aug 2020 11:22:42

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	06 Aug 2020 11:22:42
	System	06 Aug 2020 11:22:42

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	06 Aug 2020 11:22:42
	System	06 Aug 2020 11:22:42

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	06 Aug 2020 11:22:42
	System	06 Aug 2020 11:22:42

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	06 Aug 2020 11:22:42
	System	06 Aug 2020 11:22:42

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	06 Aug 2020 11:22:42
	System	06 Aug 2020 11:22:42

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '06 Aug 2020 07:22'	System	06 Aug 2020 11:22:42
	System	06 Aug 2020 11:22:42

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	07 Aug 2020 10:34:29
	System	07 Aug 2020 10:34:29

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	07 Aug 2020 10:34:29
	System	07 Aug 2020 10:34:29

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	07 Aug 2020 10:34:29
	System	07 Aug 2020 10:34:29

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	07 Aug 2020 10:34:29
	System	07 Aug 2020 10:34:29

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	07 Aug 2020 10:34:29
	System	07 Aug 2020 10:34:29

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	07 Aug 2020 10:34:29
	System	07 Aug 2020 10:34:29

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	07 Aug 2020 10:34:29
	System	07 Aug 2020 10:34:29

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '07 Aug 2020 06:34'	System	07 Aug 2020 10:34:29
	System	07 Aug 2020 10:34:29

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' 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: 10 Jun 2021 09:50:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' 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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	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: 10 Jun 2021 09:50:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '07 Aug 2020 12:55'	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: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	09 Aug 2020 01:58:01
	System	09 Aug 2020 01:58:01

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	09 Aug 2020 01:58:01
	System	09 Aug 2020 01:58:01

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	09 Aug 2020 01:58:01
	System	09 Aug 2020 01:58:01

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	09 Aug 2020 01:58:01
	System	09 Aug 2020 01:58:01

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	09 Aug 2020 01:58:01
	System	09 Aug 2020 01:58:01

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	09 Aug 2020 01:58:01
	System	09 Aug 2020 01:58:01

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	09 Aug 2020 01:58:01
	System	09 Aug 2020 01:58:01

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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
	System	09 Aug 2020 01:58:01

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	10 Aug 2020 02:12:31
	System	10 Aug 2020 02:12:31

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	10 Aug 2020 02:12:31
	System	10 Aug 2020 02:12:31

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	10 Aug 2020 02:12:31
	System	10 Aug 2020 02:12:31

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	10 Aug 2020 02:12:31
	System	10 Aug 2020 02:12:31

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	10 Aug 2020 02:12:31
	System	10 Aug 2020 02:12:31

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	10 Aug 2020 02:12:31
	System	10 Aug 2020 02:12:31

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	10 Aug 2020 02:12:31
	System	10 Aug 2020 02:12:31

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '09 Aug 2020 22:12'	System	10 Aug 2020 02:12:31
	System	10 Aug 2020 02:12:31

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	11 Aug 2020 02:12:15
	System	11 Aug 2020 02:12:15

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	11 Aug 2020 02:12:15
	System	11 Aug 2020 02:12:15

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	11 Aug 2020 02:12:15
	System	11 Aug 2020 02:12:15

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	11 Aug 2020 02:12:15
	System	11 Aug 2020 02:12:15

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	11 Aug 2020 02:12:15
	System	11 Aug 2020 02:12:15

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	11 Aug 2020 02:12:15
	System	11 Aug 2020 02:12:15

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '10 Aug 2020 22:12'	System	11 Aug 2020 02:12:15
	System	11 Aug 2020 02:12:15

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	12 Aug 2020 02:07:13
	System	12 Aug 2020 02:07:13

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	12 Aug 2020 02:07:13
	System	12 Aug 2020 02:07:13

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	12 Aug 2020 02:07:13
	System	12 Aug 2020 02:07:13

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	12 Aug 2020 02:07:13
	System	12 Aug 2020 02:07:13

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	12 Aug 2020 02:07:13
	System	12 Aug 2020 02:07:13

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	12 Aug 2020 02:07:13
	System	12 Aug 2020 02:07:13

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	12 Aug 2020 02:07:13
	System	12 Aug 2020 02:07:13

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:38:21
User entered empty.	Kelly Woodell (b) (4) (b) (4)	25 Aug 2020 22:39:51

US3822015

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:25:55
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	25 Aug 2020 22:39:54

US3822015

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'I'	System	25 Aug 2020 22:39:54

US3822015

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'I'	System	25 Aug 2020 22:40:07

US3822015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 16:01:13
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	03 Sep 2020 15:59:09

US3822015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 16:01:13
User entered '27 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	03 Sep 2020 15:59:09

US3822015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 16:01:13
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4) (b) (4)	03 Sep 2020 15:59:09

US3822015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 16:01:13
User entered empty.	Kelly Woodell (b) (4) (b) (4)	03 Sep 2020 15:59:09

US3822015

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'I'	System	03 Sep 2020 15:57:33

US3822015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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) (b) (4)	28 Sep 2020 21:32:33
User opened query 'Please complete all Visit 2 EDC pages.' (Site from CRA).	(b) (4), (b) (6)	22 Sep 2020 19:14:09
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	03 Sep 2020 15:57:50

US3822015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:35:42
User entered '03 Sep 2020'	Kelly Woodell (b) (4) (b) (4)	03 Sep 2020 15:57:50

US3822015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:35:42
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4) (b) (4)	03 Sep 2020 15:57:50

US3822015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'VISIT2'	System	03 Sep 2020 15:57:50

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
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: 10 Jun 2021 09:50:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
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: 10 Jun 2021 09:50:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'bpm'	System	28 Sep 2020 21:27:12

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
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: 10 Jun 2021 09:50:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:36:12
User entered '120'	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: 10 Jun 2021 09:50:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'mmHg'	System	28 Sep 2020 21:27:12

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'mmHg'	System	28 Sep 2020 21:27:12

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
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: 10 Jun 2021 09:50:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
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: 10 Jun 2021 09:50:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'bpm'	System	28 Sep 2020 21:27:42

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
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: 10 Jun 2021 09:50:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:36:12
User entered '121'	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: 10 Jun 2021 09:50:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'mmHg'	System	28 Sep 2020 21:27:42

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:36:12
User entered '81'	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: 10 Jun 2021 09:50:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'mmHg'	System	28 Sep 2020 21:27:42

US3822015

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:37:53
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	03 Sep 2020 15:58:09

US3822015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:37:53
User entered empty.	Kelly Woodell (b) (4) (b) (4)	03 Sep 2020 15:58:09

US3822015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:37:53
User entered empty.	Kelly Woodell (b) (4) (b) (4)	03 Sep 2020 15:58:09

US3822015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 15:58:09

US3822015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:37:53
User entered '03 Sep 2020'	Kelly Woodell (b) (4) (b) (4)	03 Sep 2020 15:58:09

US3822015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
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: 10 Jun 2021 09:50:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:37:53
User entered 'Left Arm (LEFT ARM)'	Kelly Woodell (b) (4) (b) (4)	03 Sep 2020 15:58:09

US3822015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
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: 10 Jun 2021 09:50:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 15:58:09

US3822015

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
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: 10 Jun 2021 09:50:28

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:38:29
User entered '3 Sep 2020'	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: 10 Jun 2021 09:50:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
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: 10 Jun 2021 09:50:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
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: 10 Jun 2021 09:50:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	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: 10 Jun 2021 09:50:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered empty.	System	28 Sep 2020 21:28:22

US3822015

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'I'	System	28 Sep 2020 21:28:26

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'Yes (Y)'	System	03 Sep 2020 16:10:52
	System	03 Sep 2020 16:10:52

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '98.4'	System	03 Sep 2020 16:10:52
	System	03 Sep 2020 16:10:52

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '03 Sep 2020 12:10'	System	03 Sep 2020 16:10:52
	System	03 Sep 2020 16:10:52

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'Yes (Y)'	System	04 Sep 2020 01:33:33
	System	04 Sep 2020 01:33:33

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '97.9'	System	04 Sep 2020 01:33:33
	System	04 Sep 2020 01:33:33

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	04 Sep 2020 01:33:33
	System	04 Sep 2020 01:33:33

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '03 Sep 2020 21:33'	System	04 Sep 2020 01:33:33
	System	04 Sep 2020 01:33:33

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'Yes (Y)'	System	05 Sep 2020 01:48:19
	System	05 Sep 2020 01:48:19

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '97.3'	System	05 Sep 2020 01:48:19
	System	05 Sep 2020 01:48:19

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	05 Sep 2020 01:48:19
	System	05 Sep 2020 01:48:19

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '04 Sep 2020 21:48'	System	05 Sep 2020 01:48:19
	System	05 Sep 2020 01:48:19

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'Yes (Y)'	System	06 Sep 2020 02:15:45
	System	06 Sep 2020 02:15:45

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '97.4'	System	06 Sep 2020 02:15:45
	System	06 Sep 2020 02:15:45

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	06 Sep 2020 02:15:45
	System	06 Sep 2020 02:15:45

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '05 Sep 2020 22:15'	System	06 Sep 2020 02:15:45
	System	06 Sep 2020 02:15:45

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'Yes (Y)'	System	07 Sep 2020 01:56:12
	System	07 Sep 2020 01:56:12

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '97.4'	System	07 Sep 2020 01:56:12
	System	07 Sep 2020 01:56:12

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '06 Sep 2020 21:56'	System	07 Sep 2020 01:56:12
	System	07 Sep 2020 01:56:12

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'Yes (Y)'	System	08 Sep 2020 02:08:17
	System	08 Sep 2020 02:08:17

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '97.8'	System	08 Sep 2020 02:08:17
	System	08 Sep 2020 02:08:17

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	08 Sep 2020 02:08:17
	System	08 Sep 2020 02:08:17

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '07 Sep 2020 22:08'	System	08 Sep 2020 02:08:17
	System	08 Sep 2020 02:08:17

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'Yes (Y)'	System	09 Sep 2020 00:58:36
	System	09 Sep 2020 00:58:36

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '97.4'	System	09 Sep 2020 00:58:36
	System	09 Sep 2020 00:58:36

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	09 Sep 2020 00:58:36
	System	09 Sep 2020 00:58:36

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '08 Sep 2020 20:58'	System	09 Sep 2020 00:58:36
	System	09 Sep 2020 00:58:36

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'Yes (Y)'	System	10 Sep 2020 00:21:04
	System	10 Sep 2020 00:21:04

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '98.2'	System	10 Sep 2020 00:21:04
	System	10 Sep 2020 00:21:04

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '09 Sep 2020 20:21'	System	10 Sep 2020 00:21:04
	System	10 Sep 2020 00:21:04

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	03 Sep 2020 16:11:42
	System	03 Sep 2020 16:11:42

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	03 Sep 2020 16:11:42
	System	03 Sep 2020 16:11:42

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '03 Sep 2020 12:11'	System	03 Sep 2020 16:11:42
	System	03 Sep 2020 16:11:42

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '03 Sep 2020 21:34'	System	04 Sep 2020 01:34:54
	System	04 Sep 2020 01:34:54

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	05 Sep 2020 01:49:48
	System	05 Sep 2020 01:49:48

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	05 Sep 2020 01:49:48
	System	05 Sep 2020 01:49:48

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '04 Sep 2020 21:49'	System	05 Sep 2020 01:49:48
	System	05 Sep 2020 01:49:48

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' 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: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' 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: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '05 Sep 2020 22:16'	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: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (1)'	System	07 Sep 2020 01:57:23
	System	07 Sep 2020 01:57:23

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	07 Sep 2020 01:57:23
	System	07 Sep 2020 01:57:23

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	07 Sep 2020 01:57:23
	System	07 Sep 2020 01:57:23

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (1)'	System	07 Sep 2020 01:57:23
	System	07 Sep 2020 01:57:23

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '06 Sep 2020 21:57'	System	07 Sep 2020 01:57:23
	System	07 Sep 2020 01:57:23

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (1)'	System	08 Sep 2020 02:09:19
	System	08 Sep 2020 02:09:19

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	08 Sep 2020 02:09:19
	System	08 Sep 2020 02:09:19

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	08 Sep 2020 02:09:19
	System	08 Sep 2020 02:09:19

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (1)'	System	08 Sep 2020 02:09:19
	System	08 Sep 2020 02:09:19

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '07 Sep 2020 22:09'	System	08 Sep 2020 02:09:19
	System	08 Sep 2020 02:09:19

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	09 Sep 2020 00:59:25
	System	09 Sep 2020 00:59:25

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (1)'	System	09 Sep 2020 00:59:25
	System	09 Sep 2020 00:59:25

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (1)'	System	10 Sep 2020 00:22:05
	System	10 Sep 2020 00:22:05

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	10 Sep 2020 00:22:05
	System	10 Sep 2020 00:22:05

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	10 Sep 2020 00:22:05
	System	10 Sep 2020 00:22:05

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (1)'	System	10 Sep 2020 00:22:05
	System	10 Sep 2020 00:22:05

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '09 Sep 2020 20:22'	System	10 Sep 2020 00:22:05
	System	10 Sep 2020 00:22:05

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	03 Sep 2020 16:12:35
	System	03 Sep 2020 16:12:35

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	03 Sep 2020 16:12:35
	System	03 Sep 2020 16:12:35

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	03 Sep 2020 16:12:35
	System	03 Sep 2020 16:12:35

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	03 Sep 2020 16:12:35
	System	03 Sep 2020 16:12:35

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	03 Sep 2020 16:12:35
	System	03 Sep 2020 16:12:35

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	03 Sep 2020 16:12:35
	System	03 Sep 2020 16:12:35

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	03 Sep 2020 16:12:35
	System	03 Sep 2020 16:12:35

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '03 Sep 2020 12:12'	System	03 Sep 2020 16:12:35
	System	03 Sep 2020 16:12:35

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	04 Sep 2020 01:35:57
	System	04 Sep 2020 01:35:57

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	04 Sep 2020 01:35:57
	System	04 Sep 2020 01:35:57

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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
	System	04 Sep 2020 01:35:57

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	04 Sep 2020 01:35:57
	System	04 Sep 2020 01:35:57

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	04 Sep 2020 01:35:57
	System	04 Sep 2020 01:35:57

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	04 Sep 2020 01:35:57
	System	04 Sep 2020 01:35:57

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	04 Sep 2020 01:35:57
	System	04 Sep 2020 01:35:57

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '03 Sep 2020 21:35'	System	04 Sep 2020 01:35:57
	System	04 Sep 2020 01:35:57

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' 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: 10 Jun 2021 09:50:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' 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: 10 Jun 2021 09:50:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' 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: 10 Jun 2021 09:50:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	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: 10 Jun 2021 09:50:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '04 Sep 2020 21:51'	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: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	06 Sep 2020 02:17:40
	System	06 Sep 2020 02:17:40

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	06 Sep 2020 02:17:40
	System	06 Sep 2020 02:17:40

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	06 Sep 2020 02:17:40
	System	06 Sep 2020 02:17:40

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	06 Sep 2020 02:17:40
	System	06 Sep 2020 02:17:40

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	06 Sep 2020 02:17:40
	System	06 Sep 2020 02:17:40

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	06 Sep 2020 02:17:40
	System	06 Sep 2020 02:17:40

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	06 Sep 2020 02:17:40
	System	06 Sep 2020 02:17:40

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '05 Sep 2020 22:17'	System	06 Sep 2020 02:17:40
	System	06 Sep 2020 02:17:40

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	07 Sep 2020 01:58:36
	System	07 Sep 2020 01:58:36

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	07 Sep 2020 01:58:36
	System	07 Sep 2020 01:58:36

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	07 Sep 2020 01:58:36
	System	07 Sep 2020 01:58:36

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	07 Sep 2020 01:58:36
	System	07 Sep 2020 01:58:36

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	07 Sep 2020 01:58:36
	System	07 Sep 2020 01:58:36

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	07 Sep 2020 01:58:36
	System	07 Sep 2020 01:58:36

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	07 Sep 2020 01:58:36
	System	07 Sep 2020 01:58:36

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '06 Sep 2020 21:58'	System	07 Sep 2020 01:58:36
	System	07 Sep 2020 01:58:36

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	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: 10 Jun 2021 09:50:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '07 Sep 2020 22:10'	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: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' 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: 10 Jun 2021 09:50:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' 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: 10 Jun 2021 09:50:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' 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: 10 Jun 2021 09:50:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' 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: 10 Jun 2021 09:50:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' 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: 10 Jun 2021 09:50:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	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: 10 Jun 2021 09:50:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '08 Sep 2020 21:00'	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: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	10 Sep 2020 00:23:01
	System	10 Sep 2020 00:23:01

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	10 Sep 2020 00:23:01
	System	10 Sep 2020 00:23:01

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	10 Sep 2020 00:23:01
	System	10 Sep 2020 00:23:01

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	10 Sep 2020 00:23:01
	System	10 Sep 2020 00:23:01

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	10 Sep 2020 00:23:01
	System	10 Sep 2020 00:23:01

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'None (0)'	System	10 Sep 2020 00:23:01
	System	10 Sep 2020 00:23:01

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	10 Sep 2020 00:23:01
	System	10 Sep 2020 00:23:01

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '09 Sep 2020 20:22'	System	10 Sep 2020 00:23:01
	System	10 Sep 2020 00:23:01

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'I'	System	28 Sep 2020 21:33:04

US3822015

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'I'	System	28 Sep 2020 21:33:28

US3822015

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'I'	System	28 Sep 2020 21:33:54

US3822015

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'VISIT3'	System	05 Oct 2020 19:27:45

US3822015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
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: 10 Jun 2021 09:50:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:31:17
User entered empty.	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:29:10

US3822015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'bpm'	System	05 Oct 2020 19:29:10

US3822015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'breaths/min'	System	05 Oct 2020 19:29:10

US3822015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:31:17
User entered '122'	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:29:10

US3822015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'mmHg'	System	05 Oct 2020 19:29:10

US3822015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:31:17
User entered '80'	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:29:10

US3822015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'mmHg'	System	05 Oct 2020 19:29:10

US3822015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24

US3822015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24

US3822015

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:28

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
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) (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) (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) (b) (4)	05 Oct 2020 19:29:30

US3822015

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
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: 10 Jun 2021 09:50:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:09:20
User closed query 'Kindly add D85 to EDC as this was completed on 29OCT2020 per EMR. Thank yo. (Site from CRA).	(b) (4) (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) (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) (b) (4)	05 Oct 2020 19:27:51

US3822015

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'I'	System	05 Oct 2020 19:27:51

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	08 Oct 2020 22:00:33
	System	08 Oct 2020 22:00:33

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '08 Oct 2020 18:00:29'	System	08 Oct 2020 22:00:33
	System	08 Oct 2020 22:00:33

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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
	System	19 Oct 2020 10:09:21

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	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: 10 Jun 2021 09:50:28

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered 'No (N)'	System	16 Nov 2020 11:40:10
	System	16 Nov 2020 11:40:10

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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' User entered '16 Nov 2020 06:40:07'	System	16 Nov 2020 11:40:10
	System	16 Nov 2020 11:40:10

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:29:23
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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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' User entered 'No (N)'	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: 10 Jun 2021 09:50:28

Have you been exposed to someone with 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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: '2020-11-27T06:13:52', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'd93a2ebc-edff-433f-a196-5bba9579c639'	System	27 Nov 2020 11:14:34
User entered 'No (N)'	System	27 Nov 2020 11:14:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Have you been exposed to someone with 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: '2020-11-27T06:14:11', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'd93a2ebc-edff-433f-a196-5bba9579c639'	System	27 Nov 2020 11:14:34
User entered 'No (N)'	System	27 Nov 2020 11:14:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: '2020-11-27T06:14:31', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'd93a2ebc-edff-433f-a196-5bba9579c639' User entered '27 Nov 2020 06:14:31'	System	27 Nov 2020 11:14:34
	System	27 Nov 2020 11:14:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: '2020-12-04T07:32:23', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'db16a18d-49b9-4007-bbcf-1344ca7ea2c3'	System	04 Dec 2020 12:32:57
User entered 'No (N)'	System	04 Dec 2020 12:32:57

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Have you been exposed to someone with 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: '2020-12-04T07:32:39', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'db16a18d-49b9-4007-bbcf-1344ca7ea2c3'	System	04 Dec 2020 12:32:57
User entered 'No (N)'	System	04 Dec 2020 12:32:57

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: '2020-12-04T07:32:55', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'db16a18d-49b9-4007-bbcf-1344ca7ea2c3' User entered '04 Dec 2020 07:32:55'	System	04 Dec 2020 12:32:57
	System	04 Dec 2020 12:32:57

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: '2020-12-11T07:39:24', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '6d50cb7b-8d29-48eb-befc-d684461e098f' User entered 'No (N)'	System	11 Dec 2020 12:39:58
	System	11 Dec 2020 12:39:58

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Have you been exposed to someone with 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: '2020-12-11T07:39:36', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '6d50cb7b-8d29-48eb-befc-d684461e098f' User entered 'No (N)'	System	11 Dec 2020 12:39:58
	System	11 Dec 2020 12:39:58

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: '2020-12-11T07:39:56', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '6d50cb7b-8d29-48eb-befc-d684461e098f' User entered '11 Dec 2020 07:39:56'	System	11 Dec 2020 12:39:58
	System	11 Dec 2020 12:39:58

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: '2020-12-18T07:01:54', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'af205c2f-87c8-445f-9283-6f3e7b80dfd3'	System	18 Dec 2020 12:02:38
User entered 'No (N)'	System	18 Dec 2020 12:02:38

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Have you been exposed to someone with 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: '2020-12-18T07:02:11', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'af205c2f-87c8-445f-9283-6f3e7b80dfd3'	System	18 Dec 2020 12:02:38
User entered 'No (N)'	System	18 Dec 2020 12:02:38

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: '2020-12-18T07:02:33', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'af205c2f-87c8-445f-9283-6f3e7b80dfd3' User entered '18 Dec 2020 07:02:33'	System	18 Dec 2020 12:02:38
	System	18 Dec 2020 12:02:38

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: '2020-12-25T08:41:43', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'e54e82b2-62c7-4b19-af45-c718c4e606c0' User entered 'No (N)'	System	25 Dec 2020 13:42:01
	System	25 Dec 2020 13:42:01

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Have you been exposed to someone with 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: '2020-12-25T08:41:51', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'e54e82b2-62c7-4b19-af45-c718c4e606c0'	System	25 Dec 2020 13:42:01
User entered 'No (N)'	System	25 Dec 2020 13:42:01

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: '2020-12-25T08:41:58', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'e54e82b2-62c7-4b19-af45-c718c4e606c0' User entered '25 Dec 2020 08:41:58'	System	25 Dec 2020 13:42:01
	System	25 Dec 2020 13:42:01

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: '2021-01-01T07:25:29', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '951c6350-de11-4d34-8fe6-8c0cd46e92f5' User entered 'No (N)'	System	01 Jan 2021 12:26:08
	System	01 Jan 2021 12:26:08

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Have you been exposed to someone with 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: '2021-01-01T07:25:45', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '951c6350-de11-4d34-8fe6-8c0cd46e92f5'	System	01 Jan 2021 12:26:08
User entered 'No (N)'	System	01 Jan 2021 12:26:08

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: '2021-01-01T07:26:06', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '951c6350-de11-4d34-8fe6-8c0cd46e92f5' User entered '01 Jan 2021 07:26:06'	System	01 Jan 2021 12:26:08
	System	01 Jan 2021 12:26:08

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: '2021-01-08T07:37:57', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '47452eb4-a32d-4c44-9cf3-7c26049df8f2'	System	08 Jan 2021 12:38:32
User entered 'No (N)'	System	08 Jan 2021 12:38:32

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[Have you been exposed to someone with 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: '2021-01-08T07:38:12', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '47452eb4-a32d-4c44-9cf3-7c26049df8f2'	System	08 Jan 2021 12:38:32
User entered 'No (N)'	System	08 Jan 2021 12:38:32

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: '2021-01-08T07:38:28', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '47452eb4-a32d-4c44-9cf3-7c26049df8f2'	System	08 Jan 2021 12:38:32
User entered '08 Jan 2021 07:38:28'	System	08 Jan 2021 12:38:32

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: '2021-01-15T06:12:07', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'cdd2bd3d-18d6-486b-a1b3-f57f7373daad' User entered 'No (N)'	System	15 Jan 2021 11:12:56
	System	15 Jan 2021 11:12:56

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[Have you been exposed to someone with 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: '2021-01-15T06:12:21', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'cdd2bd3d-18d6-486b-a1b3-f57f7373daad' User entered 'No (N)'	System	15 Jan 2021 11:12:56

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: '2021-01-15T06:12:53', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'cdd2bd3d-18d6-486b-a1b3-f57f7373daad' User entered '15 Jan 2021 06:12:53'	System	15 Jan 2021 11:12:56
	System	15 Jan 2021 11:12:56

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: '2021-01-22T06:55:31', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '7bda017e-1fbe-4616-8a77-12da9598892a' User entered 'No (N)'	System	22 Jan 2021 11:56:03
	System	22 Jan 2021 11:56:03

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Have you been exposed to someone with 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: '2021-01-22T06:55:22', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '7bda017e-1fbe-4616-8a77-12da9598892a' User entered 'No (N)'	System	22 Jan 2021 11:56:03
	System	22 Jan 2021 11:56:03

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: '2021-01-22T06:55:59', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '7bda017e-1fbe-4616-8a77-12da9598892a' User entered '22 Jan 2021 06:55:59'	System	22 Jan 2021 11:56:03
	System	22 Jan 2021 11:56:03

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: '2021-01-29T07:22:12', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a98af287-17f5-4a99-93fc-d3dd0ba8dadc' User entered 'No (N)'	System	29 Jan 2021 12:22:55

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Have you been exposed to someone with 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: '2021-01-29T07:22:46', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a98af287-17f5-4a99-93fc-d3dd0ba8dadc' User entered 'No (N)'	System	29 Jan 2021 12:22:55

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: '2021-01-29T07:22:53', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a98af287-17f5-4a99-93fc-d3dd0ba8dadc' User entered '29 Jan 2021 07:22:53'	System	29 Jan 2021 12:22:55
	System	29 Jan 2021 12:22:55

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: '2021-02-05T07:09:13', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'c3b163dd-a236-4722-9571-cb73df2292ed' User entered 'No (N)'	System	05 Feb 2021 12:10:08

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Have you been exposed to someone with 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: '2021-02-05T07:09:30', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'c3b163dd-a236-4722-9571-cb73df2292ed' User entered 'No (N)'	System	05 Feb 2021 12:10:08

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: '2021-02-05T07:10:05', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'c3b163dd-a236-4722-9571-cb73df2292ed' User entered '05 Feb 2021 07:10:05'	System	05 Feb 2021 12:10:08
	System	05 Feb 2021 12:10:08

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: '2021-02-12T06:24:28', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a5d61de5-9d75-4ba3-b9c6-88523cbbe6f2' User entered 'No (N)'	System	12 Feb 2021 11:25:11
	System	12 Feb 2021 11:25:11

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Have you been exposed to someone with 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: '2021-02-12T06:24:54', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a5d61de5-9d75-4ba3-b9c6-88523cbbe6f2'	System	12 Feb 2021 11:25:11
User entered 'No (N)'	System	12 Feb 2021 11:25:11

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: '2021-02-12T06:25:09', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a5d61de5-9d75-4ba3-b9c6-88523cbbe6f2' User entered '12 Feb 2021 06:25:09'	System	12 Feb 2021 11:25:11
	System	12 Feb 2021 11:25:11

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: '2021-02-19T07:49:57', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '846a5d8d-777f-4a85-ad23-58e8e87e291e' User entered 'No (N)'	System	19 Feb 2021 12:50:22
	System	19 Feb 2021 12:50:22

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Have you been exposed to someone with 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: '2021-02-19T07:50:11', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '846a5d8d-777f-4a85-ad23-58e8e87e291e' User entered 'No (N)'	System	19 Feb 2021 12:50:22
	System	19 Feb 2021 12:50:22

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: '2021-02-19T07:50:20', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '846a5d8d-777f-4a85-ad23-58e8e87e291e' User entered '19 Feb 2021 07:50:20'	System	19 Feb 2021 12:50:22
	System	19 Feb 2021 12:50:22

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: '2021-02-26T07:15:48', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '13413288-dc52-4800-9a6a-137d04b39d3b' User entered 'No (N)'	System	26 Feb 2021 12:16:18
	System	26 Feb 2021 12:16:18

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Have you been exposed to someone with 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: '2021-02-26T07:16:00', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '13413288-dc52-4800-9a6a-137d04b39d3b' User entered 'No (N)'	System	26 Feb 2021 12:16:18
	System	26 Feb 2021 12:16:18

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: '2021-02-26T07:16:11', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '13413288-dc52-4800-9a6a-137d04b39d3b' User entered '26 Feb 2021 07:16:11'	System	26 Feb 2021 12:16:18
	System	26 Feb 2021 12:16:18

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: '2021-03-05T06:53:38', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '1d92f8e6-5bf5-4720-966b-1aed8699df5b' User entered 'No (N)'	System	05 Mar 2021 11:54:11

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Have you been exposed to someone with 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: '2021-03-05T06:53:57', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '1d92f8e6-5bf5-4720-966b-1aed8699df5b'	System	05 Mar 2021 11:54:11
User entered 'No (N)'	System	05 Mar 2021 11:54:11

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: '2021-03-05T06:54:09', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '1d92f8e6-5bf5-4720-966b-1aed8699df5b' User entered '05 Mar 2021 06:54:09'	System	05 Mar 2021 11:54:11
	System	05 Mar 2021 11:54:11

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: '2021-03-12T06:49:32', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'f09467e4-3657-4235-92c0-ca4671bf9cdf'	System	12 Mar 2021 11:50:52
User entered 'No (N)'	System	12 Mar 2021 11:50:52

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Have you been exposed to someone with 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: '2021-03-12T06:50:30', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'f09467e4-3657-4235-92c0-ca4671bf9cdf'	System	12 Mar 2021 11:50:52
User entered 'No (N)'	System	12 Mar 2021 11:50:52

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: '2021-03-12T06:50:49', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'f09467e4-3657-4235-92c0-ca4671bf9cdf' User entered '12 Mar 2021 06:50:49'	System	12 Mar 2021 11:50:52
	System	12 Mar 2021 11:50:52

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: '2021-03-19T07:11:21', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'cf31cf0a-cabd-4ab4-b42e-0cdca1ac5c54'	System	19 Mar 2021 11:12:00
User entered 'No (N)'	System	19 Mar 2021 11:12:00

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Have you been exposed to someone with 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: '2021-03-19T07:11:40', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'cf31cf0a-cabd-4ab4-b42e-0cdca1ac5c54'	System	19 Mar 2021 11:12:00
User entered 'No (N)'	System	19 Mar 2021 11:12:00

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: '2021-03-19T07:11:57', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'cf31cf0a-cabd-4ab4-b42e-0cdca1ac5c54' User entered '19 Mar 2021 07:11:57'	System	19 Mar 2021 11:12:00
	System	19 Mar 2021 11:12:00

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: '2021-03-26T06:53:12', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '603f83b5-c9c4-4522-80a2-1c045b703ef5'	System	26 Mar 2021 10:53:42
User entered 'No (N)'	System	26 Mar 2021 10:53:42

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Have you been exposed to someone with 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: '2021-03-26T06:53:26', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '603f83b5-c9c4-4522-80a2-1c045b703ef5'	System	26 Mar 2021 10:53:42
User entered 'No (N)'	System	26 Mar 2021 10:53:42

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: '2021-03-26T06:53:39', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '603f83b5-c9c4-4522-80a2-1c045b703ef5' User entered '26 Mar 2021 06:53:39'	System	26 Mar 2021 10:53:42
	System	26 Mar 2021 10:53:42

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: '2021-04-02T07:43:55', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '69984ce8-f3cc-48b0-a366-d95b3c680659' User entered 'No (N)'	System	02 Apr 2021 11:44:24
	System	02 Apr 2021 11:44:24

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Have you been exposed to someone with 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: '2021-04-02T07:44:09', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '69984ce8-f3cc-48b0-a366-d95b3c680659' User entered 'No (N)'	System	02 Apr 2021 11:44:24
	System	02 Apr 2021 11:44:24

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: '2021-04-02T07:44:22', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '69984ce8-f3cc-48b0-a366-d95b3c680659' User entered '02 Apr 2021 07:44:22'	System	02 Apr 2021 11:44:24
	System	02 Apr 2021 11:44:24

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: '2021-04-09T06:33:22', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '8dee9a01-34ec-47a6-9f7d-3c2601f312f4'	System	09 Apr 2021 10:34:00
User entered 'No (N)'	System	09 Apr 2021 10:34:00

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[Have you been exposed to someone with 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: '2021-04-09T06:33:37', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '8dee9a01-34ec-47a6-9f7d-3c2601f312f4' User entered 'No (N)'	System	09 Apr 2021 10:34:00

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: '2021-04-09T06:33:57', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '8dee9a01-34ec-47a6-9f7d-3c2601f312f4'	System	09 Apr 2021 10:34:00
User entered '09 Apr 2021 06:33:57'	System	09 Apr 2021 10:34:00

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: '2021-04-16T07:03:43', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a866a9ea-4d36-45af-aed0-baa716461a52'	System	16 Apr 2021 11:04:07
User entered 'No (N)'	System	16 Apr 2021 11:04:07

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Have you been exposed to someone with 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: '2021-04-16T07:03:56', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a866a9ea-4d36-45af-aed0-baa716461a52'	System	16 Apr 2021 11:04:07
User entered 'No (N)'	System	16 Apr 2021 11:04:07

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: '2021-04-16T07:04:04', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a866a9ea-4d36-45af-aed0-baa716461a52'	System	16 Apr 2021 11:04:07
User entered '16 Apr 2021 07:04:04'	System	16 Apr 2021 11:04:07

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: '2021-04-23T06:46:51', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '9b3768be-0339-4358-8a7b-c9acaf1bd31d' User entered 'No (N)'	System	23 Apr 2021 10:47:14
	System	23 Apr 2021 10:47:14

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Have you been exposed to someone with 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: '2021-04-23T06:47:07', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '9b3768be-0339-4358-8a7b-c9acaf1bd31d' User entered 'No (N)'	System	23 Apr 2021 10:47:14
	System	23 Apr 2021 10:47:14

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: '2021-04-23T06:47:12', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '9b3768be-0339-4358-8a7b-c9acaf1bd31d' User entered '23 Apr 2021 06:47:12'	System	23 Apr 2021 10:47:14
	System	23 Apr 2021 10:47:14

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: '2021-04-30T06:55:16', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'bc3afa80-5379-4e59-9b9c-a36d007d511d' User entered 'No (N)'	System	30 Apr 2021 10:55:51

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

Have you been exposed to someone with 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: '2021-04-30T06:55:34', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'bc3afa80-5379-4e59-9b9c-a36d007d511d' User entered 'No (N)'	System	30 Apr 2021 10:55:51

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: '2021-04-30T06:55:48', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'bc3afa80-5379-4e59-9b9c-a36d007d511d' User entered '30 Apr 2021 06:55:48'	System	30 Apr 2021 10:55:51
	System	30 Apr 2021 10:55:51

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:50:28

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:20:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2021-03-05T06:54:29', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '7a7cf06a-ee96-4ff9-80aa-9c11bf71acf1'	System	05 Mar 2021 11:54:48
User entered 'No (N)'	System	05 Mar 2021 11:54:48

US3822015

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:50:28

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:20:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2021-03-05T06:54:46', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '7a7cf06a-ee96-4ff9-80aa-9c11bf71acf1' User entered '05 Mar 2021 06:54:46'	System	05 Mar 2021 11:54:48
	System	05 Mar 2021 11:54:48

US3822015

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:05:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:19:12
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:09:27

US3822015

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:05:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:19:12
User entered '29 Oct 2020'	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:09:27

US3822015

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:05:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:19:12
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:09:27

US3822015

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:05:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:19:12
User entered empty.	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:09:27

US3822015

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:05:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:19:56
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:09:34

US3822015

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:33:24
User entered 'I'	System	05 Nov 2020 01:09:34

US3822015

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:33:48
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:11:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Jan 2021 14:26:48

US3822015

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:33:48
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:11:20
User entered '03 Dec 2020'	(b) (4), (b) (6)	05 Jan 2021 14:26:48

US3822015

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:33:48
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:11:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Jan 2021 14:26:48

US3822015

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:33:48
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:11:20
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 14:26:48

US3822015

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:33:48
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:11:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Jan 2021 14:26:51

US3822015

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:33:48
User entered 'I'	System	05 Jan 2021 14:26:51

US3822015

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:33:48
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:58:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Jan 2021 14:27:02

US3822015

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:33:48
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:58:30
User entered '31 Dec 2020'	(b) (4), (b) (6)	05 Jan 2021 14:27:02

US3822015

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:33:48
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:58:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Jan 2021 14:27:02

US3822015

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:33:48
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:58:30
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 14:27:02

US3822015

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:33:48
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:58:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Jan 2021 14:27:06

US3822015

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:33:48
User entered 'I'	System	05 Jan 2021 14:27:06

US3822015

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:33:48
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:32:10
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	11 Feb 2021 20:02:17

US3822015

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:33:48
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:32:10
User entered '28 Jan 2021'	Kelly Woodell (b) (4) (b) (4)	11 Feb 2021 20:02:17

US3822015

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:33:48
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:32:10
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4) (b) (4)	11 Feb 2021 20:02:17

US3822015

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:33:48
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:32:10
User entered empty.	Kelly Woodell (b) (4) (b) (4)	11 Feb 2021 20:02:17

US3822015

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:33:48
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:32:21
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	11 Feb 2021 20:02:21

US3822015

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:33:48
User entered 'I'	System	11 Feb 2021 20:02:21

US3822015

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 17:37:28

US3822015

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:24
User entered '15 Mar 2021'	(b) (4), (b) (6)	15 Mar 2021 17:37:28

US3822015

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:24
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Mar 2021 17:37:28

US3822015

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User entered 'VISIT4'	System	15 Mar 2021 17:37:28

US3822015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:38:52
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:08:04

US3822015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:38:52
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:08:04

US3822015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:38:52
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:08:04

US3822015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User entered empty.	System	30 Mar 2021 15:08:04

US3822015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:38:52
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:08:04

US3822015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:38:52
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:08:04

US3822015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:38:52
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:08:04

US3822015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:38:52
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:08:04

US3822015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User entered empty.	System	30 Mar 2021 15:08:04

US3822015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:38:52
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:08:04

US3822015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User entered empty.	System	30 Mar 2021 15:08:04

US3822015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:38:52
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:08:04

US3822015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User entered empty.	System	30 Mar 2021 15:08:04

US3822015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:38:52
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:08:04

US3822015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User entered empty.	System	30 Mar 2021 15:08:04

US3822015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 10:17:57

US3822015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 10:17:57

US3822015

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:36
User entered 'No (N)'	(b) (4), (b) (6)	15 Mar 2021 17:37:31

US3822015

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:36
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 17:37:31

US3822015

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 17:37:36

US3822015

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:28

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:41
User entered '15 Mar 2021'	(b) (4), (b) (6)	15 Mar 2021 17:37:36

US3822015

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:28

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:41
User entered '11:45'	(b) (4), (b) (6)	15 Mar 2021 17:37:36

US3822015

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:28

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User entered '15 Mar 2021 11:45'	System	15 Mar 2021 17:37:36

US3822015

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:22:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 17:37:39

US3822015

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:57
User entered 'I'	System	15 Mar 2021 17:37:39

US3822015

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	11 Apr 2021 23:55:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 12:37:58

US3822015

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	11 Apr 2021 23:55:49
User entered '01 Apr 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 12:37:58

US3822015

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	11 Apr 2021 23:55:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 12:37:58

US3822015

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	11 Apr 2021 23:55:49
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 12:37:58

US3822015

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	11 Apr 2021 23:55:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 12:38:43

US3822015

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 12:38:43

US3822015

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

Form: Visit Date

Generated On: 10 Jun 2021 09:50:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:57:41
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	13 Jan 2021 16:33:15
	(b) (4)	

US3822015

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

Form: Visit Date

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:57:41
User entered '11 Jan 2021'	Kelly Woodell (b) (4)	13 Jan 2021 16:33:15
	(b) (4)	

US3822015

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

Form: Visit Date

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:57:41
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4)	13 Jan 2021 16:33:15
	(b) (4)	

US3822015

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

Form: Visit Date

Generated On: 10 Jun 2021 09:50:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 16:33:15

US3822015

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

Form: Unblinding

Generated On: 10 Jun 2021 09:50:28

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:29:24
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:57:50
User entered '11 Jan 2021'	Kelly Woodell (b) (4) (b) (4)	13 Jan 2021 16:33:28

US3822015

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

Form: Unblinding

Generated On: 10 Jun 2021 09:50:28

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:29:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:13:24
User signature succeeded.	Christina Kennelly (b) (4)	11 Apr 2021 23:55:49
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 13:22:04
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:18:21

US3822015

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

Form: Unblinding

Generated On: 10 Jun 2021 09:50:28

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:29:24
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:57:50
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	13 Jan 2021 16:33:28

US3822015

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

Form: Unblinding

Generated On: 10 Jun 2021 09:50:28

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:29:24
User closed query 'Per CDM: Per Sponsor review: 'Under what version of the Protocol was the participant unblinded?' is blank - Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 05:46:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:13:24
User signature succeeded.	Christina Kennelly (b) (4)	11 Apr 2021 23:55:49
Query 'Per CDM: Per Sponsor review: 'Under what version of the Protocol was the participant unblinded?' is blank - Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. Thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 13:22:57
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	08 Apr 2021 13:22:04
User opened query 'Per CDM: Per Sponsor review: 'Under what version of the Protocol was the participant unblinded?' is blank - Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 09:58:00
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:18:21

US3822015

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

Form: Unblinding

Generated On: 10 Jun 2021 09:50:28

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:29:24
User signature succeeded.	Christina Kennelly (b) (4)	28 Apr 2021 06:15:38
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:40:57
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4), (b) (6)	26 Apr 2021 08:35:02
User closed query 'Per CDM: Re-query, response below noted. According to IRT, assignment unblinding was completed on 10Jan21. As per the memo sent to sites regarding Unblinding eCRF instructions on 13Apr dated 7Apr, this date must be the date the transaction happened in IRT. Please enter the unblinding date per IRT.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 08:35:00
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'Subject unblinded in IRT on 10JAN2021 after verbally agreeing to be unblinded and appointment scheduled, but not officially unblinded in clinic until 11JAN2021 after signing consent.' (Site from System).	(b) (4), (b) (6)	23 Apr 2021 13:31:26
Query 'Per CDM: Re-query, response below noted. According to IRT, assignment unblinding was completed on 10Jan21. As per the memo sent to sites regarding Unblinding eCRF instructions on 13Apr dated 7Apr, this date must be the date the transaction happened in IRT. Please enter the unblinding date per IRT.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 13:30:59
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	23 Apr 2021 13:30:43
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 13:30:43
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 13:30:43
User entered '10 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 13:30:43

US3822015

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

Form: Unblinding

Generated On: 10 Jun 2021 09:50:28

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per CDM: Re-query, response below noted. According to IRT, assignment unblinding was completed on 10Jan21. As per the memo sent to sites regarding Unblinding eCRF instructions on 13Apr dated 7Apr, this date must be the date the transaction happened in IRT. Please enter the unblinding date per IRT.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 13:00:21
User closed query 'Per CDM RQ: Response noted. However, this field is the date of unblinding in IRT. Please reconcile. Thank you' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 13:00:21
Query 'Per CDM RQ: Response noted. However, this field is the date of unblinding in IRT. Please reconcile. Thank you' answered with 'As previously stated, patient not unblinded in clinic until 11JAN2021 even though, they were unblinded in IRT prior to their appointment in clinic.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 12:51:05
User opened query 'Per CDM RQ: Response noted. However, this field is the date of unblinding in IRT. Please reconcile. Thank you' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 12:42:00
User closed query 'Per CDM : Per IRT : subject was unblinded on 10JAN2021. Please review and reconcile. Thank you' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 12:42:00
Query 'Per CDM : Per IRT : subject was unblinded on 10JAN2021. Please review and reconcile. Thank you' answered with 'Subject unblinding in IRT done on 10JAN2021 but SUBJECT was actually unblinded in clinic 11JAN2021.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 13:22:40
User opened query 'Per CDM : Per IRT : subject was unblinded on 10JAN2021. Please review and reconcile. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:02:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:57:50
User entered '11 Jan 2021'	Kelly Woodell (b) (4)	13 Jan 2021 16:33:28

US3822015

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

Form: Unblinding

Generated On: 10 Jun 2021 09:50:28

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:29:24
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:57:50
User entered 'Placebo (Placebo)'	Kelly Woodell (b) (4) (b) (4)	13 Jan 2021 16:33:28

US3822015

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

Form: Unblinding

Generated On: 10 Jun 2021 09:50:28

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:29:24
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:57:50
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 11:20:46
User entered 'Placebo (Placebo)'	Kelly Woodell (b) (4) (b) (4)	13 Jan 2021 16:33:28

US3822015

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

Form: Unblinding

Generated On: 10 Jun 2021 09:50:28

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:29:24
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:57:50
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 11:20:46
User entered 'Placebo (Placebo)'	Kelly Woodell (b) (4) (b) (4)	13 Jan 2021 16:33:28

US3822015

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

Form: Unblinding

Generated On: 10 Jun 2021 09:50:28

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:29:24
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:57:50
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	13 Jan 2021 16:33:28

US3822015

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

Form: Unblinding

Generated On: 10 Jun 2021 09:50:28

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:29:24
User entered '1'	System	13 Jan 2021 16:33:28

US3822015

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

Form: Unblinding

Generated On: 10 Jun 2021 09:50:28

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:29:24
User entered 'I'	System	13 Jan 2021 16:33:28

US3822015

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:50:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:58:38
User entered '68' in	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:50:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:58:38
User entered '185.2' lb	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:50:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered '28.21844'	System	13 Jan 2021 16:34:24
DataPoint set to visible.	System	13 Jan 2021 16:33:28

US3822015

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:50:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 16:58:38
User entered '68' in	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:50:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 16:58:38
User entered '185.2' lb	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:50:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered '28.21844'	System	13 Jan 2021 16:34:24
DataPoint set to visible.	System	13 Jan 2021 16:33:28

US3822015

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User accepted default value 'Pre-Dose (PREDOSE)'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 16:58:38
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 16:58:38
User entered '11 Jan 2021'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 16:58:38
User entered '14:53'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered '11 Jan 2021 14:53'	System	13 Jan 2021 16:34:24

US3822015

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:58:38
User entered '98.0' F	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 16:58:38
User entered 'Oral (Oral)'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 16:58:38
User entered empty.	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 16:58:38
User entered '80'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered 'bpm'	System	13 Jan 2021 16:34:24

US3822015

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 16:58:38
User entered '14'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered 'breaths/min'	System	13 Jan 2021 16:34:24

US3822015

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 16:58:38
User entered '117'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered 'mmHg'	System	13 Jan 2021 16:34:24

US3822015

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 16:58:38
User entered '72'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered 'mmHg'	System	13 Jan 2021 16:34:24

US3822015

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:50:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:58:38
User entered '68' in	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:50:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:58:38
User entered '185.2' lb	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:50:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered '28.21844'	System	13 Jan 2021 16:34:24
DataPoint set to visible.	System	13 Jan 2021 16:33:28

US3822015

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User accepted default value 'Post-Dose (POSTDOSE)'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:58:38
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 16:58:38
User entered '11 Jan 2021'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:58:38
User entered '16:00'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered '11 Jan 2021 16:00'	System	13 Jan 2021 16:34:24

US3822015

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:58:38
User entered '97.8' F	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:58:38
User entered 'Oral (Oral)'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:58:38
User entered empty.	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:58:38
User entered '80'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered 'bpm'	System	13 Jan 2021 16:34:24

US3822015

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:58:38
User entered '14'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered 'breaths/min'	System	13 Jan 2021 16:34:24

US3822015

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:58:38
User entered '129'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered 'mmHg'	System	13 Jan 2021 16:34:24

US3822015

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 16:58:38
User entered '84'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:24
	(b) (4)	

US3822015

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered 'mmHg'	System	13 Jan 2021 16:34:24

US3822015

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:59:50
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:29
	(b) (4)	

US3822015

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 16:59:50
User entered '11 Jan 2021'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:29
	(b) (4)	

US3822015

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

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:59:57
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:40
	(b) (4)	

US3822015

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

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:59:57
User entered empty.	Kelly Woodell (b) (4)	13 Jan 2021 16:34:40
	(b) (4)	

US3822015

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

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:59:57
User entered empty.	Kelly Woodell (b) (4)	13 Jan 2021 16:34:40
	(b) (4)	

US3822015

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

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered 'mRNA-1273'	System	13 Jan 2021 16:34:40
DataPoint set to visible.	System	13 Jan 2021 16:33:28

US3822015

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

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 16:59:57
User entered '11 Jan 2021'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:40
	(b) (4)	

US3822015

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

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:59:57
User entered '15:25'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:40
	(b) (4)	

US3822015

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

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered '11 Jan 2021 15:25'	System	13 Jan 2021 16:34:40

US3822015

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

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:59:57
User entered 'Left Arm (LEFT ARM)'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:40
	(b) (4)	

US3822015

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

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 16:59:57
User entered 'ONCE'	System	13 Jan 2021 16:34:40

US3822015

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

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered 'INTRAMUSCULAR'	System	13 Jan 2021 16:34:40

US3822015

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:00:20
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:49
	(b) (4)	

US3822015

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 17:00:20
User entered '11 Jan 2021'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:49
	(b) (4)	

US3822015

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:00:20
User entered '14:58'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:49
	(b) (4)	

US3822015

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:28

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered '11 Jan 2021 14:58'	System	13 Jan 2021 16:34:49

US3822015

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:50:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:01:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:58
	(b) (4)	

US3822015

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:50:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:01:03
User entered '11 Jan 2021'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:58
	(b) (4)	

US3822015

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:50:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:01:03
User entered '15:15'	Kelly Woodell (b) (4)	13 Jan 2021 16:34:58
	(b) (4)	

US3822015

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:50:28

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered '11 Jan 2021 15:15'	System	13 Jan 2021 16:34:58

US3822015

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

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:01:09
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	13 Jan 2021 16:35:00
	(b) (4)	

US3822015

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

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered 'I'	System	13 Jan 2021 16:35:00

US3822015

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:34
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 20:40:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 18:41:55

US3822015

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:34
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 20:40:56
User entered '20 Jan 2021'	(b) (4), (b) (6)	09 Feb 2021 18:41:55

US3822015

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:34
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 20:40:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Feb 2021 18:41:55

US3822015

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:34
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 20:40:56
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 18:41:55

US3822015

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:34
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 20:40:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 18:42:03

US3822015

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:34
User entered 'I'	System	09 Feb 2021 18:42:03

US3822015

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:34
User entered 'I'	System	09 Feb 2021 18:42:03
DataPoint set to visible.	System	09 Feb 2021 18:42:03

US3822015

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 18:42:19

US3822015

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:33
User entered '08 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 18:42:19

US3822015

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 19:47:33
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	09 Feb 2021 18:42:19

US3822015

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered 'OLD29'	System	09 Feb 2021 18:42:19

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	09 Feb 2021 18:42:43

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 19:47:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 18:42:43

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 19:47:38
User entered '08 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 18:42:43

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:38
User entered '13:10'	(b) (4), (b) (6)	09 Feb 2021 18:42:43

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered '08 Feb 2021 13:10'	System	09 Feb 2021 18:42:43

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:38
User entered '98.7' F	(b) (4), (b) (6)	09 Feb 2021 18:42:43

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:38
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Feb 2021 18:42:43

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:38
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 18:42:43

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:38
User entered '76'	(b) (4), (b) (6)	09 Feb 2021 18:42:43

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered 'bpm'	System	09 Feb 2021 18:42:43

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:38
User entered '20'	(b) (4), (b) (6)	09 Feb 2021 18:42:43

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered 'breaths/min'	System	09 Feb 2021 18:42:43

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:38
User entered '117'	(b) (4), (b) (6)	09 Feb 2021 18:42:43

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered 'mmHg'	System	09 Feb 2021 18:42:43

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:38
User entered '77'	(b) (4), (b) (6)	09 Feb 2021 18:42:43

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered 'mmHg'	System	09 Feb 2021 18:42:43

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	09 Feb 2021 18:43:12

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 19:47:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 18:43:12

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 19:47:38
User entered '08 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 18:43:12

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:38
User entered '14:00'	(b) (4), (b) (6)	09 Feb 2021 18:43:12

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered '08 Feb 2021 14:00'	System	09 Feb 2021 18:43:12

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:38
User entered '98.2' F	(b) (4), (b) (6)	09 Feb 2021 18:43:12

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:38
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Feb 2021 18:43:12

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:38
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 18:43:12

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:38
User entered '80'	(b) (4), (b) (6)	09 Feb 2021 18:43:12

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered 'bpm'	System	09 Feb 2021 18:43:12

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:38
User entered '20'	(b) (4), (b) (6)	09 Feb 2021 18:43:12

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered 'breaths/min'	System	09 Feb 2021 18:43:12

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:38
User entered '107'	(b) (4), (b) (6)	09 Feb 2021 18:43:12

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered 'mmHg'	System	09 Feb 2021 18:43:12

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:38
User entered '69'	(b) (4), (b) (6)	09 Feb 2021 18:43:12

US3822015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered 'mmHg'	System	09 Feb 2021 18:43:12

US3822015

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:48:12
User entered 'No (N)'	(b) (4), (b) (6)	09 Feb 2021 18:44:45

US3822015

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:28

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:48:12
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 18:44:45

US3822015

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:48:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 18:44:58

US3822015

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:48:17
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 18:44:58

US3822015

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:48:17
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 18:44:58

US3822015

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered 'mRNA-1273'	System	09 Feb 2021 18:44:58
DataPoint set to visible.	System	09 Feb 2021 18:42:03

US3822015

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:48:17
User entered '08 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 18:44:58

US3822015

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:48:17
User entered '13:26'	(b) (4), (b) (6)	09 Feb 2021 18:44:58

US3822015

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered '08 Feb 2021 13:26'	System	09 Feb 2021 18:44:58

US3822015

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:48:17
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	09 Feb 2021 18:44:58

US3822015

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:48:17
User entered 'ONCE'	System	09 Feb 2021 18:44:58

US3822015

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered 'INTRAMUSCULAR'	System	09 Feb 2021 18:44:58

US3822015

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 19:47:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 18:45:03

US3822015

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered 'I'	System	09 Feb 2021 18:45:03

US3822015

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:34
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 20:34:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 17:40:46

US3822015

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:34
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 20:34:11
User entered '15 Feb 2021'	(b) (4), (b) (6)	16 Feb 2021 17:40:46

US3822015

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:34
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 20:34:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Feb 2021 17:40:46

US3822015

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:34
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 20:34:11
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 17:40:46

US3822015

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:34
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 20:34:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 17:40:49

US3822015

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:34
User entered 'I'	System	16 Feb 2021 17:40:49

US3822015

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:24:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 17:37:48

US3822015

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:24:49
User entered '15 Mar 2021'	(b) (4), (b) (6)	15 Mar 2021 17:37:48

US3822015

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:24:49
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Mar 2021 17:37:48

US3822015

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered 'OLD57'	System	15 Mar 2021 17:37:48

US3822015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 14:24:58
User entered 'No (N)'	(b) (4), (b) (6)	15 Mar 2021 17:37:51

US3822015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:24:58
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 17:37:51

US3822015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:24:58
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 17:37:51

US3822015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered empty.	System	15 Mar 2021 17:37:51

US3822015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:24:58
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 17:37:51

US3822015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:24:58
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 17:37:51

US3822015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:24:58
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 17:37:51

US3822015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:24:58
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 17:37:51

US3822015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered empty.	System	15 Mar 2021 17:37:51

US3822015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 14:24:58
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 17:37:51

US3822015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered empty.	System	15 Mar 2021 17:37:51

US3822015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:24:58
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 17:37:51

US3822015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered empty.	System	15 Mar 2021 17:37:51

US3822015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 14:24:58
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 17:37:51

US3822015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered empty.	System	15 Mar 2021 17:37:51

US3822015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31

US3822015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:28

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31

US3822015

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:25:04
User entered 'No (N)'	(b) (4), (b) (6)	15 Mar 2021 17:38:00

US3822015

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:28

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:25:04
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 17:38:00

US3822015

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:12:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 17:38:08

US3822015

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:12:18
User entered '15 Mar 2021'	(b) (4), (b) (6)	15 Mar 2021 17:38:08

US3822015

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 14:12:18
User entered '11:45'	(b) (4), (b) (6)	15 Mar 2021 17:38:08

US3822015

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:28

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:44:31
User entered '15 Mar 2021 11:45'	System	15 Mar 2021 17:38:08

US3822015

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:50:28

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:13:51
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
Reviewed for Safety.	(b) (4) (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: 10 Jun 2021 09:50:28

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Oct 2020 15:20:15
	(b) (4)	
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
	(b) (4)	
User entered 'Heart Failure' reason for change: Data Entry Error	Kelly Woodell (b) (4)	12 Oct 2020 15:18:43
	(b) (4)	
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
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Oct 2020 19:36:22
	(b) (4)	
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
	(b) (4)	
DataPoint Un-verified.	Krishna Shah (b) (4)	05 Oct 2020 19:35:30
	(b) (4)	
Coding entries removed.	Krishna Shah (b) (4)	05 Oct 2020 19:35:30
	(b) (4)	
User entered 'Pleural effusion' reason for change: Data Entry Error	Krishna Shah (b) (4)	05 Oct 2020 19:35:30
	(b) (4)	
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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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).	(b) (4), (b) (6)	08 Oct 2020 15:29:16
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).	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 14:34:40
User entered '09 Sep 2020' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 14:34:22
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)	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) (b) (4)	28 Sep 2020 21:29:38
DataPoint Un-verified.	(b) (4), (b) (6)	22 Sep 2020 14:12:15

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
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: 10 Jun 2021 09:50:28

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
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) (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) (b) (4)	28 Sep 2020 21:31:08
User entered 'No (N)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:30:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:30:28
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:29:54
User entered 'No (N)' reason for change: Data Entry Error	Krishna Shah (b) (4) (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: 10 Jun 2021 09:50:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
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) (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) (b) (4)	05 Oct 2020 19:36:11
DataPoint Verified.	(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) (b) (4)	28 Sep 2020 21:31:48
User entered '12 Sep 2020' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:31:48
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: 10 Jun 2021 09:50:28

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

Severity

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:47:27
User closed query 'PV Query: Since the subject was hospitalized for the event of heart failure, appropriate grade should be grade 3 instead of grade 1/grade 2. Please update the event severity as such. If the severity is to remain grade 1/grade 2, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 21:52:07
Query 'PV Query: Since the subject was hospitalized for the event of heart failure, appropriate grade should be grade 3 instead of grade 1/grade 2. Please update the event severity as such. If the severity is to remain grade 1/grade 2, please clarify/explain.' answered with 'Updated' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 13:24:17
DataPoint Un-verified.	(b) (4), (b) (6)	08 Feb 2021 13:23:43
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 13:23:43
User opened query 'PV Query: Since the subject was hospitalized for the event of heart failure, appropriate grade should be grade 3 instead of grade 1/grade 2. Please update the event severity as such. If the severity is to remain grade 1/grade 2, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 12:23:53
User closed query 'Per CRIO intensity is Moderate. Please review and update CRIO or EDC as applicable.' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 14:23:08
DataPoint Verified.	(b) (4), (b) (6)	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)	12 Oct 2020 12:18:03
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(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)	08 Oct 2020 19:48:18

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
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)	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)	05 Oct 2020 19:36:01
DataPoint Un-verified.	(b) (4)	
	Krishna Shah (b) (4)	28 Sep 2020 21:30:53
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	(b) (4)	28 Sep 2020 21:30:53
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
	(b) (4), (b) (6)	
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)	17 Sep 2020 19:14:30
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	11 Sep 2020 17:57:10

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:08:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:57:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:28

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4)	22 Sep 2020 14:08:53
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 17:57:10
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 09:50:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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 'I'	(b) (4), (b) (6)	11 Sep 2020 17:57:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:28

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
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) (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

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:28

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
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) (4), (b) (6)	06 Oct 2020 14:04:14
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 14:08:53
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)	22 Sep 2020 09:23:10
Query 'PV Query: Please provide the hospital discharge date when available.' canceled (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 19:15:43
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 19:12:46
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).	(b) (4), (b) (6)	17 Sep 2020 19:12:36
User entered '12 Sep 2020' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:47:51
User opened query 'Per CDM: Please provide Discharge date. Kindly keep the query open until information is available. Thank you.' (Site from DM).	Kelly Woodell (b) (4) (b) (4), (b) (6)	16 Sep 2020 22:44:10
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 15:11:10
	(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)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4)	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: 10 Jun 2021 09:50:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4)	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)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4)	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	(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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Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:08
	(b) (4)	
Signature has been broken.	Kelly Woodell (b) (4)	23 Mar 2021 13:37:24
	(b) (4)	
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
	(b) (4)	
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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Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
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) (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) (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 'I'	(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)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4)	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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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	
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
	(b) (4)	
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
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Kelly Woodell (b) (4)	16 Sep 2020 22:44:10
	(b) (4)	
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)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	
User entered 'Continuing on oxygen' reason for change: Data Entry Error	Kelly Woodell (b) (4)	08 Oct 2020 14:41:08
	(b) (4)	
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 signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User closed query 'Per CDM: Please provide location of update such as log line number. Thank you.' (Site from DM).	(b) (4) (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) (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) (b) (4)	05 Nov 2020 00:32:23
DataPoint Un-verified.	Kelly Woodell (b) (4) (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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Folder: Adverse Events

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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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[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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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Sep 2020 17:57:10

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:28

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Sep 2020 17:57:10

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:28

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection ' (Site from DM).	(b) (4) (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) (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) (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) (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) (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) (b) (4)	08 Oct 2020 15:00:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:32:11
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:31:38
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:32:16
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:26:52
User entered '11 Sep 2020'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 15:00:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:28

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	08 Oct 2020 15:00:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:28

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
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: 10 Jun 2021 09:50:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:47:49
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 22:16:57
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'please see progress note under subject level for resolution date. ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	16 Dec 2020 20:41:45
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	16 Dec 2020 20:41:26
User entered 'No (N)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	16 Dec 2020 20:41:26
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 03:28:03
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) (b) (4)	17 Nov 2020 20:02:57
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	17 Nov 2020 20:02:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:28

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Krishna Shah (b) (4)	17 Nov 2020 20:02:50
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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 22:17:00
DataPoint Un-verified.	Krishna Shah (b) (4)	16 Dec 2020 20:41:26
User entered '12 Sep 2020' reason for change: Data Entry Error	(b) (4) Krishna Shah (b) (4)	16 Dec 2020 20:41:26
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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). DataPoint Un-verified.	System	17 Nov 2020 20:02:50
	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) (4), (b) (6)	04 Nov 2020 15:33:37
User entered empty.	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:28

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
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)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:28

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User entered empty.	System	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:33:39
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:33:41
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:28

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:33:45
User entered '0'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:28

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered '0'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered '0'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:28

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:33:48
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: 10 Jun 2021 09:50:28

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:33:48
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: 10 Jun 2021 09:50:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered empty.	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered empty.	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered '0'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered '0'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered '0'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered 'Not Related (NOT RELATED)'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered 'Not Related (NOT RELATED)'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:28

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered 'I'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered '0'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered '0'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:28

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 22:17:21
DataPoint Un-verified.	Krishna Shah (b) (4)	16 Dec 2020 20:41:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Krishna Shah (b) (4)	16 Dec 2020 20:41:26
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	(b) (4) 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) (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:33:48
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: 10 Jun 2021 09:50:28

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:33:48
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: 10 Jun 2021 09:50:28

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User entered '0'	System	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:28

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15
User entered '0'	System	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:28

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:15

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:28

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:28

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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) (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) (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) (b) (4)	17 Nov 2020 20:03:57
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	17 Nov 2020 20:03:49
User entered 'BILATERAL EDEMA, legs' reason for change: Data Entry Error	Krishna Shah (b) (4) (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) (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) (b) (4)	06 Nov 2020 23:01:12

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:28

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User entered empty.	System	06 Nov 2020 23:01:12

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:28

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User entered empty.	System	06 Nov 2020 23:01:12

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:28

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:28

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered 'I'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 23:01:12

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User entered '0'	System	06 Nov 2020 23:01:12

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:28

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19
User entered 'I'	System	06 Nov 2020 23:01:12

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:28

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:08:19

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 14:53:28
DataPoint Un-verified.	(b) (4), (b) (6)	08 Feb 2021 20:48:51
User entered empty; reason for change New Information	(b) (4), (b) (6)	08 Feb 2021 20:48:51
User closed query 'Unable to locate data in CRIO, please update.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 18:01:21
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:59:31
Query 'Unable to locate data in CRIO, please update.' answered with 'see progress note in patient's chart' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 20:12:45
User opened query 'Unable to locate data in CRIO, please update.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 15:34:33
User entered 'USA-US126-2020-mRNA-1273-P301000002'	(b) (4), (b) (6)	02 Feb 2021 17:35:15

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Nerve injuries NEC, PT: Phrenic nerve injury, LLT: Phrenic nerve injury - version MedDRA\\23.0.	Coder Import (b) (4)	08 Feb 2021 00:13:52
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Feb 2021 00:13:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 17:59:31
Data point term sent to Coder	System	01 Feb 2021 18:31:57
User entered 'Phrenic nerve damage'	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:59:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
	(b) (4)	
User closed query 'Please confirm "no" if applicable.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 19:42:34
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:42:32
	(b) (4)	
Query 'Please confirm "no" if applicable.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 18:09:35
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:30
	(b) (4)	
User opened query 'Please confirm "no" if applicable.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 18:00:42
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 18:00:14
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:59:31
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:59:31
User entered 'No (N)'	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:59:31
User entered '09 Sep 2020'	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:59:31
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 12:17:38
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' answered with 'Nerve damage is still ongoing' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 15:18:54
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 02:38:57
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:59:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 18:31:47

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
Query 'PV Query: Please provide the event end date for the events, atrial fibrillation and phrenic nerve damage when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:25:17
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), for the events,atrial fibrillation and phrenic nerve damage when available' canceled (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 17:25:13
User opened query 'PV Query: Please provide the event end date for the events, atrial fibrillation and phrenic nerve damage when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 12:22:06
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), for the events,atrial fibrillation and phrenic nerve damage when available' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 12:21:33
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:59:31
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:59:31
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:59:31
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:59:31
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	05 Feb 2021 15:54:59
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	05 Feb 2021 15:52:13
User entered 'No (N)' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	05 Feb 2021 15:52:13
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	01 Feb 2021 18:32:12
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	01 Feb 2021 18:31:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:59:31
User entered '0'	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:59:31
User entered '0'	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:59:31
User entered '0' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:54:59
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) (4), (b) (6)	03 Feb 2021 15:38:36
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 'updated' (Site from System).	(b) (4), (b) (6)	01 Feb 2021 18:33:55
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		01 Feb 2021 18:32:12
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	01 Feb 2021 18:32:12
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	01 Feb 2021 18:32:12
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Feb 2021 18:32:12
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	01 Feb 2021 18:31:47
User entered '0'	(b) (4), (b) (6)	01 Feb 2021 18:31:47

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Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:59:31
User entered empty; reason for change Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:54:59
	(b) (4)	
User entered '09 Sep 2020'	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:59:31
User entered empty; reason for change Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:54:59
	(b) (4)	
User entered '13 Sep 2020'	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:59:31
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:59:31
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:59:31
User entered '0'	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:59:31
User entered '0'	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

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Form: Adverse Events (5)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:59:31
User entered '0'	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:59:31
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:59:31
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:52:47
User closed query 'PV Query: As the last dose of [study drug] 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)	08 Feb 2021 20:48:13
Query 'PV Query: As the last dose of [study drug] 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).	(b) (4), (b) (6)	08 Feb 2021 18:08:44
DataPoint Un-verified.	(b) (4), (b) (6)	08 Feb 2021 18:08:31
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 18:08:31
User opened query 'PV Query: As the last dose of [study drug] 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)	08 Feb 2021 12:25:04
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:59:31
User entered 'None (NONE)'	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

None

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:59:31
User entered '0'	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User closed query 'Per CDM Re-Query: Site response noted; however, please note that neither CM#6 Metoprolol, nor CM#16 Metoprolol have an indication "Phrenic Nerve Damage". Please review the conmeds and ensure indication is reconciled with this AE term. Else clarify. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 10:41:12
Query 'Per CDM Re-Query: Site response noted; however, please note that neither CM#6 Metoprolol, nor CM#16 Metoprolol have an indication "Phrenic Nerve Damage". Please review the conmeds and ensure indication is reconciled with this AE term. Else clarify. Thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 12:59:58
User opened query 'Per CDM Re-Query: Site response noted; however, please note that neither CM#6 Metoprolol, nor CM#16 Metoprolol have an indication "Phrenic Nerve Damage". Please review the conmeds and ensure indication is reconciled with this AE term. Else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 12:42:18
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 12:42:18
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Metoprolol has already been added' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 15:21:03
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 02:39:36

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EAB) (1725)

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US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:59:31
User entered 'I'	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:59:31
User entered '0'	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
Query 'PV Query: Please provide the final event outcome for the events, atrial fibrillation and phrenic nerve damage , when available. Please keep query open until resolution is achieved' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:25:20
User opened query 'PV Query: Please provide the final event outcome for the events, atrial fibrillation and phrenic nerve damage , when available. Please keep query open until resolution is achieved' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 12:24:44
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:59:31
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	05 Feb 2021 15:54:59
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:59:31
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event phrenic nerve damage.' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:25:30
Query 'PV Query: Please consider updating event term of disease progression to include disease progression of atrial fibrillation.' canceled (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 17:25:28
Query 'PV Query: Start date is missing for current condition, left arm senile purpura, in patient medical history. Please provide. If not available please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 17:25:25
Query 'PV Query: Start date is missing for current condition, heart murmur, in patient medical history. Please provide. If not available please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 17:25:23
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event phrenic nerve damage.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 12:24:56
User opened query 'PV Query: Please consider updating event term of disease progression to include disease progression of atrial fibrillation.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 12:24:49
User opened query 'PV Query: Start date is missing for current condition, left arm senile purpura, in patient medical history. Please provide. If not available please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 12:21:11
User opened query 'PV Query: Start date is missing for current condition, heart murmur, in patient medical history. Please provide. If not available please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 12:20:53
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:59:31
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	01 Feb 2021 18:33:37
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	01 Feb 2021 18:33:37

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT SUSTAINED DAMAGE TO THE PHRENIC NERVE DURING CARDIAC ABLATION AND REQUIRED HOSPITAL STAY FROM 09SEP2020 TO 13SEP2020. PATIENTS METOPROLOL DOSE WAS CHANGED. SAE, AE, AND CON MED HISTORY HAS ALREADY BEEN UPDATED.' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Feb 2021 18:33:37
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	01 Feb 2021 18:31:47
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Feb 2021 15:52:13
User entered '1'	System	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:28

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Feb 2021 18:31:47

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Unable to locate in CRIO, please consider updating where applicabe.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:47:55
	(b) (4), (b) (6)	05 Apr 2021 19:46:11
Query 'Unable to locate in CRIO, please consider updating where applicabe.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 17:19:11
User opened query 'Unable to locate in CRIO, please consider updating where applicabe.' (Site from CRA). User signature succeeded.	(b) (4), (b) (6) Christina Kennelly (b) (4)	31 Mar 2021 14:38:19 12 Mar 2021 18:45:02
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) (b) (4)	11 Mar 2021 15:49:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 15:49:50
Data point term sent to Coder	System	10 Mar 2021 20:04:07
User entered 'Bilateral leg edema secondary to heart failure'	(b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:46:38
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:47:00
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:48:11
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Mar 2021 20:03:18
User entered 'No (N)' reason for change: Data Entry Error	System	10 Mar 2021 20:03:18
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	10 Mar 2021 20:03:07
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:48:44
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered '1 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

Start time (00:00-23:59)

Audit	User	Time (GMT)
Query 'Per CRIO start time is 00:00. Please reconcile and update where applicable. ' canceled (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 20:33:06
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 20:33:02
User opened query 'Per CRIO start time is 00:00. Please reconcile and update where applicable. ' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 19:49:45
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:50:01
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:51:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:51:50
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:52:09
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:52:35
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:53:01
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:53:15
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:53:28
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:53:42
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:53:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:54:13
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:54:28
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:54:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:54:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:55:14
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:55:33
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:55:55
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:56:09
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:56:25
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:56:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered 'I'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:56:51
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:57:08
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:57:28
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:57:46
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:45:02
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	10 Mar 2021 20:03:07

US3822015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:28

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Mar 2021 20:03:07

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:50:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:13:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Per CRIO, please add the following concomitant medications, if applicable: Tylenol PM Metoprolol Omeprazole ' (Site from CRA).	(b) (4) (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: 10 Jun 2021 09:50:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(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)	28 Sep 2020 21:14:44
	(b) (4)	
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 21:14:44
	(b) (4)	
Data point term sent to Coder	System	28 Sep 2020 21:13:25
User entered 'amlodipine'	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: 10 Jun 2021 09:50:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:18:19
DataPoint Un-verified.	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 00:32:47
User entered 'un UNK 2018' reason for change:	Kelly Woodell (b) (4)	05 Nov 2020 00:32:47
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:07:59
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: 10 Jun 2021 09:50:28

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(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.	(b) (4)	
	Kelly Woodell (b) (4)	05 Nov 2020 00:32:47
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Kelly Woodell (b) (4)	05 Nov 2020 00:32:47
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
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) (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: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Per CRIO start date is December 2019, please reconcile and update if applicable.' (Site from CRA).	(b) (4) (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) (b) (4)	05 Nov 2020 00:33:18
DataPoint Un-verified.	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 00:33:11
User entered 'UN Dec 2019' reason for change: Data Entry Error	Kelly Woodell (b) (4) (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) (b) (4)	28 Sep 2020 21:14:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Per MM, Please reconcile Indication and Route of Administration' (Site from DM).	(b) (4) (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: 10 Jun 2021 09:50:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	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) (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) (b) (4)	28 Sep 2020 21:15:42

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(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)	
	Kelly Woodell (b) (4)	05 Nov 2020 00:34:04
User entered 'once daily (QD)' reason for change:	(b) (4)	
Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 00:34:04
	(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: 10 Jun 2021 09:50:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Per CRIO, start date is 2018, please review and update if applicable.' (Site from CRA).	(b) (4) (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) (b) (4)	05 Nov 2020 00:34:25
DataPoint Un-verified.	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 00:33:57
User entered 'UN UNK 2018' reason for change: Data Entry Error	Kelly Woodell (b) (4) (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) (b) (4)	28 Sep 2020 21:15:42

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:25:47
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: 10 Jun 2021 09:50:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(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)	28 Sep 2020 21:15:42
	(b) (4)	

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(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)	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)	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)	28 Sep 2020 21:16:54
	(b) (4)	

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:50:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 09:50:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

Name of Medication

Audit	User	Time (GMT)
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)	08 Apr 2021 08:24:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 08:24:48
User signature succeeded.	Christina Kennelly (b) (4) (b) (4)	02 Apr 2021 20:00:27
Data point term sent to Coder	System	31 Mar 2021 15:22:52
Coding entries removed.	(b) (4), (b) (6)	31 Mar 2021 15:21:53
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)	16 Mar 2021 11:49:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 11:49:49
Data point term sent to Coder	System	25 Feb 2021 12:59:56
Coding entries removed.	(b) (4), (b) (6)	25 Feb 2021 12:59:48
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

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:28

[Name of Medication](#)

Audit	User	Time (GMT)
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: 10 Jun 2021 09:50:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:59:47
User closed query 'Per source indication is Paroxysmal Atrial fibrillation. Please reconcile and update where applicable.' (Site from CRA). User signature succeeded.	(b) (4), (b) (6) Christina Kennelly (b) (4)	05 Apr 2021 19:59:30 02 Apr 2021 20:00:27
Query 'Per source indication is Paroxysmal Atrial fibrillation. Please reconcile and update where applicable.' answered with 'Query Resolved' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 15:22:14
User entered 'Paroxysmal Atrial Fibrillation' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 15:21:53
User opened query 'Per source indication is Paroxysmal Atrial fibrillation. Please reconcile and update where applicable.' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 14:48:36
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 12:59:48
User entered 'VENTRICULAR PREMATURE BEATS/Phrenic Nerve Damage' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 12:59:48
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: 10 Jun 2021 09:50:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Per DM CLR-RQ: Response noted. However, no update has been made as of date. As per previous query, please update dates as appropriate. (CM start date prior to MH start date - UN UNK 2019). Else, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:10:15
Query 'Per DM CLR-RQ: Response noted. However, no update has been made as of date. As per previous query, please update dates as appropriate. (CM start date prior to MH start date - UN UNK 2019). Else, provide clarification.' answered with 'Patient started this medication in 2018. unknown start date. It was changed to 25 mg on 9SEP2020' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 14:56:42
User opened query 'Per DM CLR-RQ: Response noted. However, no update has been made as of date. As per previous query, please update dates as appropriate. (CM start date prior to MH start date - UN UNK 2019). Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 13:07:47
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) (b) (4)	05 Nov 2020 00:36:08
DataPoint Un-verified.	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 00:36:05
User entered 'UN UNK 2018' reason for change: Data Entry Error	Kelly Woodell (b) (4) (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) (b) (4)	28 Sep 2020 21:18:48

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	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)	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)	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)	28 Sep 2020 21:22:06
Data point term sent to Coder User entered 'tamsulosin'	System Krishna Shah (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: 10 Jun 2021 09:50:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 07:45:48
DataPoint Verified.	(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) (b) (4)	05 Nov 2020 00:45:53
Query 'Kindly spell out indication. Thank you.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 00:37:08
DataPoint Un-verified.	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 00:37:00
User entered 'Benign prostatic hyperplasia' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 00:37:00
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) (b) (4)	28 Sep 2020 21:20:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(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.	(b) (4)	
	Kelly Woodell (b) (4)	05 Nov 2020 00:37:00
User entered 'UN UNK 2018' reason for change: Data Entry Error	(b) (4)	
	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'	(b) (4)	
	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: 10 Jun 2021 09:50:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
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.	(b) (4) Coder Import (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)	05 Nov 2020 00:57:35
Data point term sent to Coder Coding entries removed.	System Kelly Woodell (b) (4)	05 Nov 2020 00:57:13 05 Nov 2020 00:56:19
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: 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)	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)	28 Sep 2020 21:22:55
Data point term sent to Coder User entered 'testosterone cypionate'	System Krishna Shah (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: 10 Jun 2021 09:50:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(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)	05 Nov 2020 00:56:32
DataPoint Un-verified.	(b) (4)	
	Kelly Woodell (b) (4)	05 Nov 2020 00:56:19
User entered 'Topical (TOPICAL)' reason for change: Data Entry Error	(b) (4)	
	Kelly Woodell (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)	28 Sep 2020 21:20:51
	(b) (4)	

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Per CRIO, start date is noted as 2018. Please review and reconcile if applicable.' (Site from CRA).	(b) (4) (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) (b) (4)	05 Nov 2020 00:56:35
DataPoint Un-verified.	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 00:56:19
User entered 'UN UNK 2018' reason for change: Data Entry Error	Kelly Woodell (b) (4) (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) (b) (4)	28 Sep 2020 21:20:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
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.	(b) (4) Coder Import (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)	05 Nov 2020 01:00:40
Data point term sent to Coder Coding entries removed.	System Kelly Woodell (b) (4)	05 Nov 2020 00:59:15 05 Nov 2020 00:58:53
DataPoint Verified.	(b) (4) (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)	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)	28 Sep 2020 21:22:49
Data point term sent to Coder User entered 'tylenol'	System Krishna Shah (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: 10 Jun 2021 09:50:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Per CRIO, reason is noted as unknown. Please review and reconcile if applicable.' (Site from CRA).	(b) (4) (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) (b) (4)	05 Nov 2020 00:58:58
DataPoint Un-verified.	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 00:58:53
User entered 'Unknown' reason for change: Data Entry Error	Kelly Woodell (b) (4) (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) (b) (4)	28 Sep 2020 21:21:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Per CRIO, dose is noted as 500. Please review and reconcile if applicable.' (Site from CRA).	(b) (4) (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) (b) (4)	05 Nov 2020 00:59:01
DataPoint Un-verified.	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 00:58:53
User entered '500' reason for change: Data Entry Error	Kelly Woodell (b) (4) (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) (b) (4)	28 Sep 2020 21:21:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
Query 'Per CRIO, dose is noted as 500mg. Please review and reconcile if applicable.' canceled (Site from CRA).	(b) (4) (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: 10 Jun 2021 09:50:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Per CRIO, frequency is noted as twice daily. Please review and reconcile if applicable.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:30:02
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:29:58
Query 'Per CRIO, frequency is noted as twice daily. Please review and reconcile if applicable.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 00:59:03
DataPoint Un-verified.	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 00:58:53
User entered 'twice daily (BID)' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 00:58:53
User opened query 'Per CRIO, frequency is noted as twice daily. Please review and reconcile if applicable.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 16:06:32
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 21:21:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Per CRIO, start date is noted as 2020. Please review and reconcile if applicable.' (Site from CRA).	(b) (4) (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) (b) (4)	05 Nov 2020 00:59:07
DataPoint Un-verified.	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 00:58:53
User entered 'UN UNK 2020' reason for change: Data Entry Error	Kelly Woodell (b) (4) (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) (b) (4)	28 Sep 2020 21:21:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:44
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) (b) (4)	19 Apr 2021 06:02:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 06:02:26
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Please add Influenza vaccine to CRIO source documentation.' (Site from CRA).	(b) (4) (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) (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) (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) (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) (b) (4)	28 Sep 2020 21:24:06

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:28

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	28 Sep 2020 21:24:06
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
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
	(b) (4)	

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:44
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: 10 Jun 2021 09:50:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:44
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: 10 Jun 2021 09:50:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:44
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: 10 Jun 2021 09:50:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Please add Pneumococcal vaccine to CRIO source documentation.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:31:08
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
Query 'Please add Pneumococcal vaccine to CRIO source documentation.' answered with 'added' (Site from CRA).	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:01:36
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:40:54
User opened query 'Please add Pneumococcal vaccine to CRIO source documentation.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 17:40:51
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: 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: 10 Jun 2021 09:50:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:20
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: 10 Jun 2021 09:50:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:20
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: 10 Jun 2021 09:50:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:20
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: 10 Jun 2021 09:50:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:23
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Please add Pneumococcal vaccine to CRIO source documentation.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:33:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
Query 'Please add Pneumococcal vaccine to CRIO source documentation.' answered with 'added' (Site from CRA).	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:02:33
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:42:57
User opened query 'Please add Pneumococcal vaccine to CRIO source documentation.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 17:42:55
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: 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: 10 Jun 2021 09:50:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:23
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:23
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:23
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:23
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:23
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:23
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:23
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:23
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:23
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:23
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:23
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:23
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:23
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:23
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:23
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: 10 Jun 2021 09:50:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:23
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: 10 Jun 2021 09:50:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:23
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: 10 Jun 2021 09:50:28

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:51
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 09:05:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 09:05:53
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Please add Zoster vaccine to CRIO source documentation.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:33:46
DataPoint Verified.	(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).	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:03:19
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:44:10
User opened query 'Please add Zoster vaccine to CRIO source documentation.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 17:44:08
DataPoint Verified.	(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, PRODUCTS YNOM: ZOSTER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (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) (b) (4)	28 Sep 2020 21:26:10
Data point term sent to Coder User entered 'zoster'	System Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:24:54 28 Sep 2020 21:24:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:51
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: 10 Jun 2021 09:50:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:51
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: 10 Jun 2021 09:50:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:51
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: 10 Jun 2021 09:50:28

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:30
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
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)	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)	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)	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)	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)	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)	05 Oct 2020 19:38:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:30
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:30
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Per CRIO, indication is heart failure. Please review and reconcile, if applicable.' (Site from CRA).	(b) (4) (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) (b) (4)	05 Nov 2020 01:04:47
DataPoint Un-verified.	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:04:09
User entered 'Heart failure' reason for change: Data Entry Error	Kelly Woodell (b) (4) (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 'pleuural effusion'	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: 10 Jun 2021 09:50:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:30
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:30
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:30
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 13:34:07
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'This is the correct units for the amount of oxygen the patient received in the hospital. ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 17:58:07
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 05:54:05
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: 10 Jun 2021 09:50:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:30
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:30
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:30
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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) (b) (4)	06 Nov 2020 22:56:40
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 22:56:33
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	Krishna Shah (b) (4) (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) (b) (4)	05 Oct 2020 19:38:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:30
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:30
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:30
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:30
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update if appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 16:40:30
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:03:45
Query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update if appropriate. Otherwise, clarify continued use after AE resolution.' answered with 'updated ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 17:59:14
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 17:59:06
User entered 'No (N)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 17:59:06
User opened query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update if appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 00:08:43
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: 10 Jun 2021 09:50:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:30
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Unable to locate end date in EMR, kindly provide source. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:12:55
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 15:12:52
Query 'Unable to locate end date in EMR, kindly provide source. ' answered with 'The end date is date of discharge from hospital. No further Oxygen was given. ' (Site from CRA).	Krishna Shah (b) (4) (b) (4)	16 Dec 2020 20:14:40
User opened query 'Unable to locate end date in EMR, kindly provide source. ' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 16:05:53
DataPoint Un-verified.	(b) (4), (b) (6)	16 Dec 2020 16:05:23
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:03:47
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 17:59:06
User entered '12 Sep 2020' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 17:59:06
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: 10 Jun 2021 09:50:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:30
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
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) (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: 10 Jun 2021 09:50:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:30
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: 10 Jun 2021 09:50:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:30
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: 10 Jun 2021 09:50:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:30
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: 10 Jun 2021 09:50:28

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
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)	26 Jan 2021 11:09:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 11:09:07
Data point term sent to Coder	System	25 Jan 2021 15:58:56
Coding entries removed.	(b) (4), (b) (6)	25 Jan 2021 15:57:56
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)	15 Dec 2020 18:01:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Dec 2020 18:01:53
Data point term sent to Coder	System	15 Dec 2020 18:01:07
Coding entries removed.	Krishna Shah (b) (4)	15 Dec 2020 18:00:54
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)	05 Nov 2020 04:46:35

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:50:28

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'Tylenol PM'	Coder Import (b) (4) (b) (4) System Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 04:46:35 05 Nov 2020 01:13:22 05 Nov 2020 01:13:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:50:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'No (N)'	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: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 16:34:39
User closed query 'Per CRIO ConMed source, the Indication is Obstructive Sleep Apnea. Please review and update CRIO if applicable.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 16:34:34
Query 'Per CRIO ConMed source, the Indication is Obstructive Sleep Apnea. Please review and update CRIO if applicable.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 15:58:13
User entered 'Obstructive Sleep Apnea' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:57:56
User opened query 'Per CRIO ConMed source, the Indication is Obstructive Sleep Apnea. Please review and update CRIO if applicable.' (Site from CRA).	(b) (4), (b) (6)	22 Jan 2021 14:21:22
User closed query 'Per EMR this con med is indicated for this indication, kindly confirm and update EMR/EDC accordingly "Obstructive sleep apnea syndrome"' (Site from CRA).	(b) (4), (b) (6)	22 Jan 2021 14:19:25
Query 'Per EMR this con med is indicated for this indication, kindly confirm and update EMR/EDC accordingly "Obstructive sleep apnea syndrome" answered with 'Not sure where in EMR this information was found but tylenol PM is not given for obstructive sleep apnea. ' (Site from CRA).	Krishna Shah (b) (4)	16 Dec 2020 20:33:30
	(b) (4)	
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 16:40:36
User opened query 'Per EMR this con med is indicated for this indication, kindly confirm and update EMR/EDC accordingly "Obstructive sleep apnea syndrome"' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 16:09:48
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'updated ' (Site from DM).	Krishna Shah (b) (4)	15 Dec 2020 18:01:01
	(b) (4)	

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 18:00:54
User entered 'insomnia' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 18:00:54
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 05:54:27
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'Obstructive sleep apnea syndrome'	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: 10 Jun 2021 09:50:28

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 10:38:04
' (Site from DM).		
Query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).	(b) (4), (b) (6)	05 Mar 2021 17:37:43
' answered with 'updated' (Site from DM).		
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 17:37:37
User entered '500/25' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 17:37:37
User opened query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).	(b) (4), (b) (6)	05 Mar 2021 14:10:44
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered '500'	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: 10 Jun 2021 09:50:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'once daily (QD)'	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: 10 Jun 2021 09:50:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'Oral (ORAL)'	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: 10 Jun 2021 09:50:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'un UNK 2019'	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: 10 Jun 2021 09:50:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered '0'	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: 10 Jun 2021 09:50:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'Yes (Y)'	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: 10 Jun 2021 09:50:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'No (N)'	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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Per DM CLR: Con Med METOPROLOL SUCCINATE was added/changed on 09 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM). Query 'Per DM CLR: Con Med METOPROLOL SUCCINATE was added/changed on 09 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' answered with 'see AE log line 4' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:37:48
User opened query 'Per DM CLR: Con Med METOPROLOL SUCCINATE was added/changed on 09 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 18:36:19
User closed query 'Per EMR this con med is listed as "Metoprolol Succinate" please update name of medication. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	31 Jan 2021 02:44:38
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.	(b) (4), (b) (6)	21 Dec 2020 15:13:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6)	21 Dec 2020 15:13:34
Data point term sent to Coder	Coder Import (b) (4) (b) (4)	16 Dec 2020 20:36:00
	Coder Import (b) (4) (b) (4)	16 Dec 2020 20:36:00
	System	16 Dec 2020 20:34:46

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:50:28

Name of Medication

Audit	User	Time (GMT)
Query 'Per EMR this con med is listed as "Metoprolol Succinate" please update name of medication. ' answered with 'updated ' (Site from CRA).	Krishna Shah (b) (4)	16 Dec 2020 20:34:01
DataPoint Un-verified.	Krishna Shah (b) (4)	16 Dec 2020 20:33:55
Coding entries removed.	Krishna Shah (b) (4)	16 Dec 2020 20:33:55
User entered 'METOPROLOL succinate' reason for change: Data Entry Error	Krishna Shah (b) (4)	16 Dec 2020 20:33:55
User opened query 'Per EMR this con med is listed as "Metoprolol Succinate" please update name of medication. ' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 16:11:28
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)	15 Dec 2020 18:04:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Dec 2020 18:04:53
Data point term sent to Coder	System	15 Dec 2020 18:04:12
Coding entries removed.	Krishna Shah (b) (4)	15 Dec 2020 18:04:02
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)	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)	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)	05 Nov 2020 01:14:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:50:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'No (N)'	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: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 16:40:39
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:11:30
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 18:04:08
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 18:04:02
User entered 'ATRIAL FIBRILLATION' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 18:04:02
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 05:55:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'Cardiac ablation'	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: 10 Jun 2021 09:50:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered '25'	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: 10 Jun 2021 09:50:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'mg (mg)'	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: 10 Jun 2021 09:50:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'once daily (QD)'	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: 10 Jun 2021 09:50:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'Oral (ORAL)'	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: 10 Jun 2021 09:50:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered '09 Sep 2020'	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: 10 Jun 2021 09:50:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered '0'	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: 10 Jun 2021 09:50:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'Yes (Y)'	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: 10 Jun 2021 09:50:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'No (N)'	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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	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: 10 Jun 2021 09:50:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed 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) (4), (b) (6)	02 Dec 2020 03:49:06
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: 10 Jun 2021 09:50:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered '20'	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: 10 Jun 2021 09:50:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'mg (mg)'	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: 10 Jun 2021 09:50:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'twice daily (BID)'	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: 10 Jun 2021 09:50:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'Oral (ORAL)'	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: 10 Jun 2021 09:50:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered '09 Sep 2020'	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: 10 Jun 2021 09:50:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered '0'	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: 10 Jun 2021 09:50:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'Yes (Y)'	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: 10 Jun 2021 09:50:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'No (N)'	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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

[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: 10 Jun 2021 09:50:28

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
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)	16 Dec 2020 10:29:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Dec 2020 10:29:25
Data point term sent to Coder	System	15 Dec 2020 18:04:11
Coding entries removed.	Krishna Shah (b) (4)	15 Dec 2020 18:03:27
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)	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)	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)	06 Nov 2020 22:53:47

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:50:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Per DM CLR: Please specify the location and/or type of EDEMA. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 16:40:50
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 16:13:17
Query 'Per DM CLR: Please specify the location and/or type of EDEMA. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' answered with 'updated ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 18:03:34
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 18:03:27
User entered 'BILATERAL EDEMA, extremities (arms/legs)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 18:03:27
User opened query 'Per DM CLR: Please specify the location and/or type of EDEMA. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 05:55:21
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: 10 Jun 2021 09:50:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:38
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: 10 Jun 2021 09:50:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:38
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: 10 Jun 2021 09:50:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:38
User entered empty.	System	06 Nov 2020 22:53:47

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:44
User closed query 'Per CDM Re-Query: Site response noted; however please confirm if this is a worsening of Atrial Fibrillation and if an AE needs to be reported. Else clarify why medication was added. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 11:56:39
Query 'Per CDM Re-Query: Site response noted; however please confirm if this is a worsening of Atrial Fibrillation and if an AE needs to be reported. Else clarify why medication was added. Thank you.' answered with 'Not for worsening. patient states that he was put on amiodarone as maintenance medication for atrial fibrillation' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 15:02:43
User opened query 'Per CDM Re-Query: Site response noted; however please confirm if this is a worsening of Atrial Fibrillation and if an AE needs to be reported. Else clarify why medication was added. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 13:38:49
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history of ATRIAL FIBRILLATION worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 13:38:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of ATRIAL FIBRILLATION worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate.' answered with 'Uncontrolled Atrial Fibrillation' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:50:11

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:28

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of ATRIAL FIBRILLATION worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 10:09:12
	(b) (4), (b) (6)	03 Feb 2021 15:38:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Feb 2021 18:40:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Feb 2021 18:40:31
Data point term sent to Coder	System	01 Feb 2021 18:40:03
User entered 'Amiodarone'	(b) (4), (b) (6)	01 Feb 2021 18:39:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:38:27
User entered 'No (N)'	(b) (4), (b) (6)	01 Feb 2021 18:39:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:38:29
User entered 'Atrial Fibrillation'	(b) (4), (b) (6)	01 Feb 2021 18:39:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:38:32
User entered '200'	(b) (4), (b) (6)	01 Feb 2021 18:39:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:38:34
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Feb 2021 18:39:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:38:39
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 18:39:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:38:42
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Feb 2021 18:39:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:38:46
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 18:39:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:38:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Feb 2021 18:39:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:38:56
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 18:39:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:44
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:06
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Per CRIO start day is 10Dec2020, please reconcile and update where applicable.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:31:18
Query 'Per CRIO start day is 10Dec2020, please reconcile and update where applicable.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 20:14:12
User entered '10 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 20:13:56
User opened query 'Per CRIO start day is 10Dec2020, please reconcile and update where applicable.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 15:39:57
User entered 'UN Dec 2020'	(b) (4), (b) (6)	01 Feb 2021 18:39:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:43:22
User entered '0'	(b) (4), (b) (6)	01 Feb 2021 18:39:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:44
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:01:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 20:01:11
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:43:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 18:39:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:44
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:01:11
User entered '27 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 20:01:11
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:43:26
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 18:39:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:44
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Per DM CLR: Please note 'Was this medication taken for solicited event?' = Yes, however, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review if this is considered a solicited local or systemic adverse reaction and if not, please update response as appropriate. Otherwise, please provide comment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 10:38:30
Query 'Per DM CLR: Please note 'Was this medication taken for solicited event?' = Yes, however, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review if this is considered a solicited local or systemic adverse reaction and if not, please update response as appropriate. Otherwise, please provide comment.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:39:06
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 12:38:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 12:38:54

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note 'Was this medication taken for solicited event?' = Yes, however, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review if this is considered a solicited local or systemic adverse reaction and if not, please update response as appropriate. Otherwise, please provide comment.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 08:31:49
	(b) (4), (b) (6)	03 Feb 2021 15:43:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 18:39:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:44
User entered '1'	System	01 Feb 2021 18:39:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:44
User entered '1'	System	01 Feb 2021 18:39:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:50:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:44
User entered '804 (804)'	System	01 Feb 2021 18:39:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:28

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
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.	(b) (4) Coder Import (b) (4) (b) (4)	09 Mar 2021 14:32:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 14:32:56
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	09 Mar 2021 14:32:05 09 Mar 2021 14:31:16
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)	16 Feb 2021 17:57:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 17:57:59
Data point term sent to Coder User entered 'LASIX'	System (b) (4), (b) (6)	16 Feb 2021 17:42:42 16 Feb 2021 17:42:03

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:28

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:42:03

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Per CDM: Response noted, however there is no AE recorded that matches this CM during this timeframe. Please verify the dates and update the data. Thank You.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 12:10:49
Query 'Per CDM: Response noted, however there is no AE recorded that matches this CM during this timeframe. Please verify the dates and update the data. Thank You.' answered with 'See AE log line 6' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 20:03:50
User opened query 'Per CDM: Response noted, however there is no AE recorded that matches this CM during this timeframe. Please verify the dates and update the data. Thank You.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 16:59:34
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.	(b) (4), (b) (6)	10 Mar 2021 16:52:50
' (Site from DM).		
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.	(b) (4), (b) (6)	09 Mar 2021 14:31:24
' answered with 'AE already added' (Site from DM).		
User entered 'HEART FAILURE' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 14:31:16
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.	(b) (4), (b) (6)	09 Mar 2021 13:18:50
' (Site from DM).		

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
User entered 'Diuretic'	(b) (4), (b) (6)	16 Feb 2021 17:42:03

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:28

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User entered '20'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:42:03

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:28

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:42:03

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:28

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:42:03

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:28

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:42:03

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:28

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:42:03

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:28

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:42:03

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:28

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:42:03

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:42:03

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:42:03

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:28

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:42:03

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:42:03

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:38
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Feb 2021 17:45:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 17:45:31
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Feb 2021 17:42:03
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 17:42:03

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 17:42:03

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 17:42:03

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:50:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Feb 2021 17:42:03

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:50:28

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:13:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
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) (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) (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) (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) (b) (4)	08 Oct 2020 14:50:53
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:34:07

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:50:28

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered '11 Sep 2020'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 14:54:47

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:50:28

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered 'CT angiography coronary artery scan'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 14:54:47

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered 'Diagnostic (DIAGNOSTIC)'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 14:54:47

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:50:28

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered empty.	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 14:54:47

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:50:28

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:33
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered '11 Sep 2020'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 14:55:20

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:50:28

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:33
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered 'CT Coronary Chest Noncardiac with Contrast'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 14:55:20

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:33
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered 'Diagnostic (DIAGNOSTIC)'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 14:55:20

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:50:28

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:33
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered empty.	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 14:55:20

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:50:28

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered '10 Sep 2020'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 14:55:55

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:50:28

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered 'Chest x-ray 1 view'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 14:55:55

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered 'Diagnostic (DIAGNOSTIC)'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 14:55:55

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:50:28

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered empty.	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 14:55:55

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:50:28

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered '12 Sep 2020'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 14:56:23

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:50:28

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered 'Chest x-ray 2 views'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 14:56:23

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered 'Diagnostic (DIAGNOSTIC)'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 14:56:23

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:50:28

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered empty.	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 14:56:23

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:50:28

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:48
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered '09 Sep 2020'	Kelly Woodell (b) (4) (b) (4)	22 Oct 2020 18:11:30

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:50:28

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:48
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered 'Cardiac Ablation'	Kelly Woodell (b) (4) (b) (4)	22 Oct 2020 18:11:30

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:48
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:53:55
User closed query 'Per CDM: CARDIAC ABLATION- indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 08:41:26
Query 'Per CDM: CARDIAC ABLATION- indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 15:39:42
DataPoint Un-verified.	(b) (4), (b) (6)	15 Mar 2021 15:39:29
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 15:39:29
User opened query 'Per CDM: CARDIAC ABLATION- indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 10:00:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered 'Medical History (MH)'	Kelly Woodell (b) (4) (b) (4)	22 Oct 2020 18:11:30

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:50:28

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:48
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered empty.	Kelly Woodell (b) (4) (b) (4)	22 Oct 2020 18:11:30

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:50:28

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:53
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:24
User entered '10 Sep 2020'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 16:46:47

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:50:28

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:53
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:24
User entered 'Echocardiogram'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 16:46:47

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:53
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:24
User entered 'Adverse Event (AE)'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 16:46:47

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:50:28

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:53
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:24
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 16:46:47

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:50:28

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:22:06
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:22:06
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:24
User entered 'Incentive spirometer'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 16:58:02

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:22:06
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:24
User entered 'Other (OTHER)'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 16:58:02

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:50:28

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:22:06
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:24
User entered 'Prophylaxis'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 16:58:02

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:50:28

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:56:02
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:14:28

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:50:28

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:56:02
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User closed query 'Per CDM: CARDIOVERSION- indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 08:41:37
Query 'Per CDM: CARDIOVERSION- indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 15:40:12
User opened query 'Per CDM: CARDIOVERSION- indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 10:26:31
User entered 'Cardioversion'	(b) (4), (b) (6)	01 Feb 2021 18:14:28

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:50:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:56:02
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:06
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	01 Feb 2021 18:14:47
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	01 Feb 2021 18:14:28
User entered 'Medical History (MH)'	(b) (4), (b) (6)	01 Feb 2021 18:14:28

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:50:28

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:56:02
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:14:47
User entered 'Cardioversion done due to atrial fibrillation event'	(b) (4), (b) (6)	01 Feb 2021 18:14:28

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Death

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 09:50:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
User closed query 'Fields not upated.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 19:42:58
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:42:56
Query 'Fields not upated.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 18:09:07
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User opened query 'Fields not upated.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:41:52
	(b) (4), (b) (6)	
User closed query 'Please update address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:41:52
	System	
User entered empty.	System	05 Feb 2021 15:54:59
Query 'Please update address fields.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 15:48:03
	(b) (4)	
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User opened query 'Please update address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:17:58
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
	System	
User entered empty.	System	02 Feb 2021 17:34:53
User closed query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 16:37:59
	(b) (4), (b) (6)	
Query 'Please complete each individual field for address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 15:58:56
	(b) (4), (b) (6)	
User entered '6060 PIEDMONT ROW DRIVE SOUTH' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
	(b) (4), (b) (6)	
User opened query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 15:48:40
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:22

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:01
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:14
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: 10 Jun 2021 09:50:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 14:53:46
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:03
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:16
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
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:05
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:18
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
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	05 Feb 2021 19:43:07
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:20
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: 10 Jun 2021 09:50:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	24 Mar 2021 17:30:44
User entered '11'	System	16 Mar 2021 17:30:42
User entered '10'	System	08 Feb 2021 20:52:38
User entered '9'	System	02 Feb 2021 17:35:48
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: 10 Jun 2021 09:50:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
User closed query 'Fields not upated.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 19:42:58
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:42:56
Query 'Fields not upated.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 18:09:07
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User opened query 'Fields not upated.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:41:52
	(b) (4), (b) (6)	
User closed query 'Please update address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:41:52
	(b) (4), (b) (6)	
User entered empty.	System	05 Feb 2021 15:54:59
Query 'Please update address fields.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 15:48:03
	(b) (4)	
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User opened query 'Please update address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:17:58
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
	(b) (4), (b) (6)	
User entered empty.	System	02 Feb 2021 17:34:53
User closed query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 16:37:59
	(b) (4), (b) (6)	
Query 'Please complete each individual field for address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 15:58:56
	(b) (4), (b) (6)	
User entered '6060 PIEDMONT ROW DRIVE SOUTH' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
	(b) (4), (b) (6)	
User opened query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 15:48:40
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:22
	(b) (4), (b) (6)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:01
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:14
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

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 14:53:46
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:03
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:16
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
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:05
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:18
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
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	05 Feb 2021 19:43:07
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:20
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: 10 Jun 2021 09:50:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	24 Mar 2021 17:30:44
User entered '11'	System	16 Mar 2021 17:30:42
User entered '10'	System	08 Feb 2021 20:52:38
User entered '9'	System	02 Feb 2021 17:35:48
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: 10 Jun 2021 09:50:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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.

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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 'I'	(b) (4), (b) (6)	12 Sep 2020 18:53:02

US3822015

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

Form: Safety Report Form

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[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(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	System	12 Sep 2020 18:50:43
'USA-US126-2020-MRNA-1273-P301000002'		

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
User closed query 'Fields not upated.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 19:42:58
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:42:56
Query 'Fields not upated.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 18:09:07
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User opened query 'Fields not upated.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:41:52
	(b) (4), (b) (6)	
User closed query 'Please update address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:41:52
	System	
User entered empty.	System	05 Feb 2021 15:54:59
Query 'Please update address fields.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 15:48:03
	(b) (4)	
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User opened query 'Please update address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:17:58
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
	System	
User entered empty.	System	02 Feb 2021 17:34:53
User closed query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 16:37:59
	(b) (4), (b) (6)	
Query 'Please complete each individual field for address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 15:58:56
	(b) (4), (b) (6)	
User entered '6060 PIEDMONT ROW DRIVE SOUTH' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
	(b) (4), (b) (6)	
User opened query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 15:48:40
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:22

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:01
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:14
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
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 14:53:46
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:03
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:16
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
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 14:53:46
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
	(b) (4), (b) (6)	
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:05
	(b) (4), (b) (6)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
	(b) (4), (b) (6)	
User entered empty.	System	02 Feb 2021 17:34:53
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
	(b) (4), (b) (6)	
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
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
	(b) (4), (b) (6)	
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23
	(b) (4)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	05 Feb 2021 19:43:07
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:20
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: 10 Jun 2021 09:50:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	24 Mar 2021 17:30:44
User entered '11'	System	16 Mar 2021 17:30:42
User entered '10'	System	08 Feb 2021 20:52:38
User entered '9'	System	02 Feb 2021 17:35:48
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: 10 Jun 2021 09:50:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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.

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:28:27
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
User entered 'I'	(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: 10 Jun 2021 09:50:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Death

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 09:50:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
User closed query 'Fields not upated.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 19:42:58
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:42:56
Query 'Fields not upated.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 18:09:07
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User opened query 'Fields not upated.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:41:52
	(b) (4), (b) (6)	
User closed query 'Please update address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:41:52
	System	
User entered empty.	System	05 Feb 2021 15:54:59
Query 'Please update address fields.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 15:48:03
	(b) (4)	
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User opened query 'Please update address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:17:58
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
	System	
User entered empty.	System	02 Feb 2021 17:34:53
User closed query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 16:37:59
	(b) (4), (b) (6)	
Query 'Please complete each individual field for address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 15:58:56
	(b) (4), (b) (6)	
User entered '6060 PIEDMONT ROW DRIVE SOUTH' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
	(b) (4), (b) (6)	
User opened query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 15:48:40
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:22

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:01
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:14
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
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:03
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:16
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
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:05
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:18
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
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	05 Feb 2021 19:43:07
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:20
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: 10 Jun 2021 09:50:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	24 Mar 2021 17:30:44
User entered '11'	System	16 Mar 2021 17:30:42
User entered '10'	System	08 Feb 2021 20:52:38
User entered '9'	System	02 Feb 2021 17:35:48
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: 10 Jun 2021 09:50:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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.

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(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 'I'	(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: 10 Jun 2021 09:50:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
User closed query 'Fields not upated.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 19:42:58
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:42:56
Query 'Fields not upated.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 18:09:07
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User opened query 'Fields not upated.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:41:52
	(b) (4), (b) (6)	
User closed query 'Please update address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:41:52
	(b) (4), (b) (6)	
User entered empty.	System	05 Feb 2021 15:54:59
Query 'Please update address fields.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 15:48:03
	(b) (4)	
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User opened query 'Please update address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:17:58
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
	(b) (4), (b) (6)	
User entered empty.	System	02 Feb 2021 17:34:53
User closed query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 16:37:59
	(b) (4), (b) (6)	
Query 'Please complete each individual field for address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 15:58:56
	(b) (4), (b) (6)	
User entered '6060 PIEDMONT ROW DRIVE SOUTH' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
	(b) (4), (b) (6)	
User opened query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 15:48:40
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:22
	(b) (4), (b) (6)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 14:53:46
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:01
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:14
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
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 14:53:46
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:03
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:16
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
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:05
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:18
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
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	05 Feb 2021 19:43:07
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:20
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: 10 Jun 2021 09:50:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	24 Mar 2021 17:30:44
User entered '11'	System	16 Mar 2021 17:30:42
User entered '10'	System	08 Feb 2021 20:52:38
User entered '9'	System	02 Feb 2021 17:35:48
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: 10 Jun 2021 09:50:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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.

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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 'I'	(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: 10 Jun 2021 09:50:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
User closed query 'Fields not upated.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 19:42:58
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:42:56
Query 'Fields not upated.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 18:09:07
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User opened query 'Fields not upated.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:41:52
	(b) (4), (b) (6)	
User closed query 'Please update address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:41:52
	System	
User entered empty.	System	05 Feb 2021 15:54:59
Query 'Please update address fields.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 15:48:03
	(b) (4)	
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User opened query 'Please update address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:17:58
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
	System	
User entered empty.	System	02 Feb 2021 17:34:53
User closed query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 16:37:59
	(b) (4), (b) (6)	
Query 'Please complete each individual field for address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 15:58:56
	(b) (4), (b) (6)	
User entered '6060 PIEDMONT ROW DRIVE SOUTH' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
	(b) (4), (b) (6)	
User opened query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 15:48:40
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:22

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 14:53:46
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:01
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:14
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
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 14:53:46
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:03
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:16
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
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:05
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:18
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
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	05 Feb 2021 19:43:07
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:20
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: 10 Jun 2021 09:50:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	24 Mar 2021 17:30:44
User entered '11'	System	16 Mar 2021 17:30:42
User entered '10'	System	08 Feb 2021 20:52:38
User entered '9'	System	02 Feb 2021 17:35:48
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: 10 Jun 2021 09:50:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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.

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(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 'I'	(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: 10 Jun 2021 09:50:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(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	System	12 Sep 2020 18:50:43
'USA-US126-2020-MRNA-1273-P301000002'		

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
User closed query 'Fields not upated.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 19:42:58
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:42:56
Query 'Fields not upated.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 18:09:07
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User opened query 'Fields not upated.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:41:52
	(b) (4), (b) (6)	
User closed query 'Please update address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:41:52
	System	
User entered empty.	System	05 Feb 2021 15:54:59
Query 'Please update address fields.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 15:48:03
	(b) (4)	
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User opened query 'Please update address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:17:58
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
	System	
User entered empty.	System	02 Feb 2021 17:34:53
User closed query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 16:37:59
	(b) (4), (b) (6)	
Query 'Please complete each individual field for address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 15:58:56
	(b) (4), (b) (6)	
User entered '6060 PIEDMONT ROW DRIVE SOUTH' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
	(b) (4), (b) (6)	
User opened query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 15:48:40
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:22

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:01
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:14
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
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 14:53:46
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
	(b) (4), (b) (6)	
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:03
	(b) (4), (b) (6)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
	(b) (4), (b) (6)	
User entered empty.	System	02 Feb 2021 17:34:53
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
	(b) (4), (b) (6)	
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
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:37
	(b) (4), (b) (6)	
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
	(b) (4), (b) (6)	
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23
	(b) (4)	

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 14:53:46
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
	(b) (4), (b) (6)	
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:05
	(b) (4), (b) (6)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
	(b) (4), (b) (6)	
User entered empty.	System	02 Feb 2021 17:34:53
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
	(b) (4), (b) (6)	
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
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
	(b) (4), (b) (6)	
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23
	(b) (4)	

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

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	05 Feb 2021 19:43:07
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:20
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

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	24 Mar 2021 17:30:44
User entered '11'	System	16 Mar 2021 17:30:42
User entered '10'	System	08 Feb 2021 20:52:38
User entered '9'	System	02 Feb 2021 17:35:48
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: 10 Jun 2021 09:50:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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.

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(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 'I'	(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: 10 Jun 2021 09:50:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
User closed query 'Fields not upated.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 19:42:58
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:42:56
Query 'Fields not upated.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 18:09:07
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User opened query 'Fields not upated.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:41:52
	(b) (4), (b) (6)	
User closed query 'Please update address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:41:52
	System	
User entered empty.	System	05 Feb 2021 15:54:59
Query 'Please update address fields.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 15:48:03
	(b) (4)	
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User opened query 'Please update address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:17:58
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
	System	
User entered empty.	System	02 Feb 2021 17:34:53
User closed query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 16:37:59
	(b) (4), (b) (6)	
Query 'Please complete each individual field for address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 15:58:56
	(b) (4), (b) (6)	
User entered '6060 PIEDMONT ROW DRIVE SOUTH' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
	(b) (4), (b) (6)	
User opened query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 15:48:40
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:22

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 14:53:46
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:01
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:14
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
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 14:53:46
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:03
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:16
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
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 14:53:46
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
	(b) (4), (b) (6)	
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:05
	(b) (4), (b) (6)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
	(b) (4), (b) (6)	
User entered empty.	System	02 Feb 2021 17:34:53
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
	(b) (4), (b) (6)	
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
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
	(b) (4), (b) (6)	
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23
	(b) (4)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	05 Feb 2021 19:43:07
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:20
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: 10 Jun 2021 09:50:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	24 Mar 2021 17:30:44
User entered '11'	System	16 Mar 2021 17:30:42
User entered '10'	System	08 Feb 2021 20:52:38
User entered '9'	System	02 Feb 2021 17:35:48
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: 10 Jun 2021 09:50:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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.

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(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 'I'	(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: 10 Jun 2021 09:50:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
User closed query 'Fields not upated.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 19:42:58
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:42:56
Query 'Fields not upated.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 18:09:07
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User opened query 'Fields not upated.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:41:52
	(b) (4), (b) (6)	
User closed query 'Please update address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:41:52
	(b) (4), (b) (6)	
User entered empty.	System	05 Feb 2021 15:54:59
Query 'Please update address fields.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 15:48:03
	(b) (4)	
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User opened query 'Please update address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:17:58
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
	(b) (4), (b) (6)	
User entered empty.	System	02 Feb 2021 17:34:53
User closed query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 16:37:59
	(b) (4), (b) (6)	
Query 'Please complete each individual field for address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 15:58:56
	(b) (4), (b) (6)	
User entered '6060 PIEDMONT ROW DRIVE SOUTH' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
	(b) (4), (b) (6)	
User opened query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 15:48:40
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:22
	(b) (4), (b) (6)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 14:53:46
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:01
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:14
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
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 14:53:46
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
	(b) (4), (b) (6)	
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:03
	(b) (4), (b) (6)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
	(b) (4), (b) (6)	
User entered empty.	System	02 Feb 2021 17:34:53
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
	(b) (4), (b) (6)	
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
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:37
	(b) (4), (b) (6)	
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
	(b) (4), (b) (6)	
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23
	(b) (4)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:05
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:18
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
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	05 Feb 2021 19:43:07
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:20
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: 10 Jun 2021 09:50:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	24 Mar 2021 17:30:44
User entered '11'	System	16 Mar 2021 17:30:42
User entered '10'	System	08 Feb 2021 20:52:38
User entered '9'	System	02 Feb 2021 17:35:48
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: 10 Jun 2021 09:50:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

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.

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:35:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
User entered 'I'	(b) (4), (b) (6)	05 Nov 2020 20:52:37

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 09:50:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
User closed query 'Fields not upated.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 19:42:58
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:42:56
Query 'Fields not upated.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 18:09:07
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User opened query 'Fields not upated.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:41:52
	(b) (4), (b) (6)	
User closed query 'Please update address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:41:52
	System	
User entered empty.	System	05 Feb 2021 15:54:59
Query 'Please update address fields.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 15:48:03
	(b) (4)	
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User opened query 'Please update address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:17:58
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
	System	
User entered empty.	System	02 Feb 2021 17:34:53
User closed query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 16:37:59
	(b) (4), (b) (6)	
Query 'Please complete each individual field for address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 15:58:56
	(b) (4), (b) (6)	
User entered '6060 PIEDMONT ROW DRIVE SOUTH' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
	(b) (4), (b) (6)	
User opened query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 15:48:40
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:22

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:01
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:14
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: 10 Jun 2021 09:50:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 14:53:46
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:03
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:16
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
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 14:53:46
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
	(b) (4), (b) (6)	
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:05
	(b) (4), (b) (6)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
	(b) (4), (b) (6)	
User entered empty.	System	02 Feb 2021 17:34:53
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
	(b) (4), (b) (6)	
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
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
	(b) (4), (b) (6)	
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23
	(b) (4)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	05 Feb 2021 19:43:07
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:20
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: 10 Jun 2021 09:50:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	24 Mar 2021 17:30:44
User entered '11'	System	16 Mar 2021 17:30:42
User entered '10'	System	08 Feb 2021 20:52:38
User entered '9'	System	02 Feb 2021 17:35:48
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 (9)

Generated On: 10 Jun 2021 09:50:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:18:43
User entered '02/Feb/2021 12:35'	System	02 Feb 2021 17:35:48

US3822015

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

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 09:50:28

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.

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 14:18:45
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered 'I'	(b) (4), (b) (6)	02 Feb 2021 17:35:48

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(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	System	12 Sep 2020 18:50:43
'USA-US126-2020-MRNA-1273-P301000002'		

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 09:50:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
User closed query 'Fields not upated.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 19:42:58
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:42:56
Query 'Fields not upated.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 18:09:07
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User opened query 'Fields not upated.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:41:52
	(b) (4), (b) (6)	
User closed query 'Please update address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:41:52
	(b) (4), (b) (6)	
User entered empty.	System	05 Feb 2021 15:54:59
Query 'Please update address fields.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 15:48:03
	(b) (4)	
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User opened query 'Please update address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:17:58
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
	(b) (4), (b) (6)	
User entered empty.	System	02 Feb 2021 17:34:53
User closed query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 16:37:59
	(b) (4), (b) (6)	
Query 'Please complete each individual field for address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 15:58:56
	(b) (4), (b) (6)	
User entered '6060 PIEDMONT ROW DRIVE SOUTH' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
	(b) (4), (b) (6)	
User opened query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 15:48:40
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:22
	(b) (4), (b) (6)	

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 14:53:46
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:01
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:14
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
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 14:53:46
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:03
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:16
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
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 14:53:46
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:05
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:18
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
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	05 Feb 2021 19:43:07
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:20
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: 10 Jun 2021 09:50:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	24 Mar 2021 17:30:44
User entered '11'	System	16 Mar 2021 17:30:42
User entered '10'	System	08 Feb 2021 20:52:38
User entered '9'	System	02 Feb 2021 17:35:48
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 (10)

Generated On: 10 Jun 2021 09:50:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 14:53:46
User entered '08/Feb/2021 20:52'	System	08 Feb 2021 20:52:38

US3822015

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

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 09:50:28

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.

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 21:55:52
User entered 'I'	(b) (4), (b) (6)	08 Feb 2021 20:52:38

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
User closed query 'Fields not upated.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 19:42:58
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:42:56
Query 'Fields not upated.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 18:09:07
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User opened query 'Fields not upated.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:41:52
	(b) (4), (b) (6)	
User closed query 'Please update address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:41:52
	System	
User entered empty.	System	05 Feb 2021 15:54:59
Query 'Please update address fields.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 15:48:03
	(b) (4)	
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User opened query 'Please update address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:17:58
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
	System	
User entered empty.	System	02 Feb 2021 17:34:53
User closed query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 16:37:59
	(b) (4), (b) (6)	
Query 'Please complete each individual field for address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 15:58:56
	(b) (4), (b) (6)	
User entered '6060 PIEDMONT ROW DRIVE SOUTH' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
	(b) (4), (b) (6)	
User opened query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 15:48:40
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:22

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

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: 10 Jun 2021 09:50:28

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 14:53:46
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:01
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:14
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
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 14:53:46
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:03
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:16
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
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 14:53:46
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:05
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:18
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
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	05 Feb 2021 19:43:07
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:20
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: 10 Jun 2021 09:50:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	24 Mar 2021 17:30:44
User entered '11'	System	16 Mar 2021 17:30:42
User entered '10'	System	08 Feb 2021 20:52:38
User entered '9'	System	02 Feb 2021 17:35:48
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 (11)

Generated On: 10 Jun 2021 09:50:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:36:02
User entered '16/Mar/2021 12:30'	System	16 Mar 2021 17:30:42

US3822015

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

Form: Safety Report Form (11)

Generated On: 10 Jun 2021 09:50:28

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.

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 17:31:32
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 13:36:02
User entered 'I'	(b) (4), (b) (6)	16 Mar 2021 17:30:42

US3822015

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

Death

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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

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

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 09:50:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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

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

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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

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

Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4) (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

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
User closed query 'Fields not upated.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 19:42:58
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:42:56
Query 'Fields not upated.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 18:09:07
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User opened query 'Fields not upated.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:41:52
	(b) (4), (b) (6)	
User closed query 'Please update address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:41:52
	System	
User entered empty.	System	05 Feb 2021 15:54:59
Query 'Please update address fields.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 15:48:03
	(b) (4)	
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User opened query 'Please update address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:17:58
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
	System	
User entered empty.	System	02 Feb 2021 17:34:53
User closed query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 16:37:59
	(b) (4), (b) (6)	
Query 'Please complete each individual field for address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 15:58:56
	(b) (4), (b) (6)	
User entered '6060 PIEDMONT ROW DRIVE SOUTH' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
	(b) (4), (b) (6)	
User opened query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 15:48:40
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:22

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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

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

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:28

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:01
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:14
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
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

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Form: Safety Report Form

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Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:03
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:16
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
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

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Form: Safety Report Form

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Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 14:53:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 20:51:46
DataPoint Un-verified.	System	08 Feb 2021 20:48:51
User entered empty.	System	08 Feb 2021 20:48:51
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:05
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 18:09:02
	(b) (4)	
User entered empty.	System	05 Feb 2021 15:54:59
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:35:52
User entered empty.	System	02 Feb 2021 17:34:53
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:58:48
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:18
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
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
	(b) (4)	
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
	(b) (4)	

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
DataPoint Verified.	(b) (4)	05 Feb 2021 19:43:07
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:48:20
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

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Form: Safety Report Form

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	24 Mar 2021 17:30:44
User entered '11'	System	16 Mar 2021 17:30:42
User entered '10'	System	08 Feb 2021 20:52:38
User entered '9'	System	02 Feb 2021 17:35:48
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

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

Form: Safety Report Form (12)

Generated On: 10 Jun 2021 09:50:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 20:33:33
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
User entered '24/Mar/2021 13:30'	(b) (4) System	24 Mar 2021 17:30:44

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Form: Safety Report Form (12)

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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)	05 Apr 2021 20:33:33
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:00:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 17:31:32
User entered 'I'	(b) (4), (b) (6)	24 Mar 2021 17:30:44