

US3822003 (Prod: Tryon Medical Partners, PLLC)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:00:59

All time stamps listed in this document are displayed in GMT

US3822003

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

Participant ID

US3822003

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

US3822003

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:02:15

Generated On: 10 Jun 2021 10:00:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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

US3822003

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 19:01:40

Generated On: 10 Jun 2021 10:00:59

Date of Birth (MMM yyyy)	(b) (6) 1955
Age	65
Age Units	YEARS
Age (Derived)	65
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

US3822003

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 19:01:40

Generated On: 10 Jun 2021 10:00:59

Date of Informed Consent (<i>dd MMM yyyy</i>)	04 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 19:01:40

Generated On: 10 Jun 2021 10:00:59

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 19:01:40

Generated On: 10 Jun 2021 10:00:59

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Feb 2021 19:01:40

Generated On: 10 Jun 2021 10:00:59

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

US3822003

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Feb 2021 19:01:40

Generated On: 10 Jun 2021 10:00:59

Condition	ATTENTION DEFICIENT HYPERACTIVITY DISORDER
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

US3822003

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 19:01:40

Generated On: 10 Jun 2021 10:00:59

Condition	CONTACT DERMATITIS - SEA LIFE, SNORKLING
Start date (dd MMM yyyy)	02 JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	9 JUL 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUL 2020
Stop Year (derived)	2020

US3822003

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 19:01:40

Generated On: 10 Jun 2021 10:00:59

Condition	BURSITIS OF OLECRANON OF RIGHT ELBOW
Start date (dd MMM yyyy)	07 MAY 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)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Feb 2021 19:01:40

Generated On: 10 Jun 2021 10:00:59

Condition	BENIGN PROSTATIC HYPERTROPHY WITH OUTFLOW OBSTRUCTION
Start date (dd MMM yyyy)	17 JUL 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)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3822003

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Feb 2021 19:01:40

Generated On: 10 Jun 2021 10:00:59

Condition	HIATAL HERNIA
Start date (dd MMM yyyy)	17 JUL 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)	JUL 2019
Start Year (derived)	2019
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 19:01:40

Generated On: 10 Jun 2021 10:00:59

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Feb 2021 19:01:40

Generated On: 10 Jun 2021 10:00:59

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	08 JAN 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)	

US3822003

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 19:02:15

Generated On: 10 Jun 2021 10:00:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	04 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:50 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 11:50
Height (<i>xxx.x</i>)	63 in
Weight (<i>xxx.x</i>)	187 lb
BMI (<i>xxx.x</i>)	33.19483 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:02:14

Generated On: 10 Jun 2021 10:00:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 19:02:14

Generated On: 10 Jun 2021 10:00:59

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 19:02:14

Generated On: 10 Jun 2021 10:00:59

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 19:02:15

Generated On: 10 Jun 2021 10:00:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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 19:02:15

Generated On: 10 Jun 2021 10:00:59

What was the date of randomization? (dd MMM yyyy) 04 AUG 2020

What was the participant's randomization number? 184619

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 19:02:15

Generated On: 10 Jun 2021 10:00:59

Height	ND - Not Done
Weight	ND - Not Done

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 19:02:15

Generated On: 10 Jun 2021 10:00:59

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)	04 AUG 2020
Time of assessment (00:00-23:59)	10:53 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 10:53
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 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: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 19:02:15

Generated On: 10 Jun 2021 10:00:59

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	04 AUG 2020
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 11:50
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	10 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG

US3822003

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:02:15

Generated On: 10 Jun 2021 10:00:59

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.

US3822003

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 19:02:15

Generated On: 10 Jun 2021 10:00:59

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) 04 AUG 2020

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

Treatment Date and Time (derived) 04 AUG 2020 11:24

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

US3822003

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:02:15

Generated On: 10 Jun 2021 10:00:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 AUG 2020
Collection time (00:00-23:59)	11:04 (24 HR)
Collection date and time (derived)	04 AUG 2020 11:04

US3822003

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 19:02:15

Generated On: 10 Jun 2021 10:00:59

Collection date (dd MMM yyyy)			04 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:10	04 AUG 2020 11:10
Nasopharyngeal Swab 2	No		

US3822003

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:02:15

Generated On: 10 Jun 2021 10:00:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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 AUG 2020 12:03

PC Open Date & Time

04 AUG 2020 11:44

PC Close Date & Time

04 AUG 2020 14:14

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

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

97.3 °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	05 AUG 2020 09:30
PC Open Date & Time	04 AUG 2020 15:09
PC Close Date & Time	05 AUG 2020 11:59

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:59

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

06 AUG 2020 09:22

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 17:00

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 17:20

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

08 AUG 2020 18:45

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

09 AUG 2020 12:09

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 15:40

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

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

04 AUG 2020 12:04

PC Open Date & Time

04 AUG 2020 11:44

PC Close Date & Time

04 AUG 2020 14:14

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

2

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 09:36

PC Open Date & Time

04 AUG 2020 15:09

PC Close Date & Time

05 AUG 2020 11:59

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

2

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 09:23

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:59

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

06 AUG 2020 17:01

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:59

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

07 AUG 2020 17:20

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:59

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

08 AUG 2020 18:45

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:59

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

09 AUG 2020 12:09

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:59

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

10 AUG 2020 15:40

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 12:05
PC Open Date & Time	04 AUG 2020 11:44
PC Close Date & Time	04 AUG 2020 14:14

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

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

No ☒

Yes ☐

PC Time stamp	05 AUG 2020 09:37
PC Open Date & Time	04 AUG 2020 15:09
PC Close Date & Time	05 AUG 2020 11:59

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:59

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 ☒

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EAB) (1725)

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US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:59

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 09:23
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:59

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)

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:59

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 17:01
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:59

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 ☒

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:59

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 17:20
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:59

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 ☒

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EAB) (1725)

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:59

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 18:46
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

57 of 2383

EAB) (1725)

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:59

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

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:59

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

59 of 2383

EAB) (1725)

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:59

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 15:40
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3822003

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:01:40

Generated On: 10 Jun 2021 10:00:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822003

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:01:40

Generated On: 10 Jun 2021 10:00:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822003

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:01:40

Generated On: 10 Jun 2021 10:00:59

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

NOT DONE

If Contact Not Made, please provide Comments

US3822003

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:01:40

Generated On: 10 Jun 2021 10:00:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822003

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:01:40

Generated On: 10 Jun 2021 10:00:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822003

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:01:40

Generated On: 10 Jun 2021 10:00:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822003

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:02:15

Generated On: 10 Jun 2021 10:00:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 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

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 19:02:15

Generated On: 10 Jun 2021 10:00:59

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)	1 SEP 2020
Time of assessment (00:00-23:59)	09:51 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 09:51
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 19:02:15

Generated On: 10 Jun 2021 10:00:59

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	1 SEP 2020
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 11:30
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3822003

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:02:15

Generated On: 10 Jun 2021 10:00:59

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.

US3822003

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 19:02:15

Generated On: 10 Jun 2021 10:00:59

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) 01 SEP 2020

What was the treatment time? (00:00-23:59) 10:56 (24 HR)

Treatment Date and Time (derived) 01 SEP 2020 10:56

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

US3822003

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:02:15

Generated On: 10 Jun 2021 10:00:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 SEP 2020
Collection time (00:00-23:59)	10:01 (24 HR)
Collection date and time (derived)	1 SEP 2020 10:01

US3822003

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 19:02:15

Generated On: 10 Jun 2021 10:00:59

Collection date (dd MMM yyyy)			1 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:30	1 SEP 2020 10:30
Nasopharyngeal Swab 2	No		

US3822003

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:02:15

Generated On: 10 Jun 2021 10:00:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

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

01 SEP 2020 11:29

PC Open Date & Time

01 SEP 2020 11:16

PC Close Date & Time

01 SEP 2020 13:46

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	01 SEP 2020 19:05
PC Open Date & Time	01 SEP 2020 14:41
PC Close Date & Time	02 SEP 2020 11:59

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:59

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	99.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False
PC Time Stamp	02 SEP 2020 16:44
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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 21:54

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:59

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

97.5 °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

04 SEP 2020 17:33

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:59

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

05 SEP 2020 19:45

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:59

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

06 SEP 2020 15:00

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 19:10

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

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

01 SEP 2020 11:30

PC Open Date & Time

01 SEP 2020 11:16

PC Close Date & Time

01 SEP 2020 13:46

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

3

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 19:06

PC Open Date & Time

01 SEP 2020 14:41

PC Close Date & Time

02 SEP 2020 11:59

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

3

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 16:45

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:59

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

03 SEP 2020 21:54

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:59

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

04 SEP 2020 17:33

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:59

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

05 SEP 2020 19:45

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:59

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

06 SEP 2020 15:01

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:59

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

07 SEP 2020 19:10

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 11:30
PC Open Date & Time	01 SEP 2020 11:16
PC Close Date & Time	01 SEP 2020 13:46

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 19:06
PC Open Date & Time	01 SEP 2020 14:41
PC Close Date & Time	02 SEP 2020 11:59

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:59

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 ☒

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EAB) (1725)

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:59

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 16:46
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

97 of 2383

EAB) (1725)

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:59

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 21:55
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:59

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 ☒

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:59

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 17:33
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:59

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 19:46
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:59

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 ☒

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:59

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 15:01
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:59

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 ☒

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:59

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 19:12
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3822003

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:01:40

Generated On: 10 Jun 2021 10:00:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822003

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:01:40

Generated On: 10 Jun 2021 10:00:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822003

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:01:40

Generated On: 10 Jun 2021 10:00:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822003

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:01:40

Generated On: 10 Jun 2021 10:00:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822003

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:01:40

Generated On: 10 Jun 2021 10:00:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822003

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:01:40

Generated On: 10 Jun 2021 10:00:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822003

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:02:15

Generated On: 10 Jun 2021 10:00:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3822003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 19:02:15

Generated On: 10 Jun 2021 10:00:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	09:49 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 09:49
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3822003

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:02:15

Generated On: 10 Jun 2021 10:00:59

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.

US3822003

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:02:15

Generated On: 10 Jun 2021 10:00:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 SEP 2020

Collection time (00:00-23:59)

09:58 (24 HR)

Collection date and time (derived)

29 SEP 2020 09:58

US3822003

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:02:15

Generated On: 10 Jun 2021 10:00:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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	06 OCT 2020 07:31:42
Patient Cloud Open Date & Time	04 OCT 2020 00:01
Patient Cloud Close Date & Time	08 OCT 2020 23:59

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission 11 OCT 2020 17:23:15

Patient Cloud Open Date & Time 11 OCT 2020 00:01

Patient Cloud Close Date & Time 15 OCT 2020 23:59

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 OCT 2020 09:30:28

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	05 NOV 2020 06:36:12
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

10 NOV 2020 22:24:59

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	15 NOV 2020 19:35:02
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 NOV 2020 10:07:42

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

28 NOV 2020 08:10:58

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

03 DEC 2020 11:16:45

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

10 DEC 2020 16:25:39

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

17 DEC 2020 06:25:01

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 08:06:33

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

31 DEC 2020 14:35:25

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

07 JAN 2021 15:06:09

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	15 JAN 2021 22:54:15
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

21 JAN 2021 08:57:29

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

28 JAN 2021 09:12:44

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 11:08:43
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 09:05:48

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 01:07:32

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 20:19:31

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

11 MAR 2021 10:54:51

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

18 MAR 2021 14:49:39

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

25 MAR 2021 12:24:22

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

01 APR 2021 11:45:38

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

08 APR 2021 12:24:26

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

18 APR 2021 17:10:02

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

22 APR 2021 14:20:51

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

29 APR 2021 10:46:20

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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="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"/>

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 292

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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="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"/>

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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"/>

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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="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"/>

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 <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"/>

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	26 JUL 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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°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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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"/>

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 411

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	20 SEP 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 <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"/>

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	27 SEP 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	25 OCT 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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°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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 <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"/>

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	27 DEC 2021 23:59
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US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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="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"/>

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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°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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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"/>

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAR 2022 00:01
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Patient Cloud Close Date & Time	28 MAR 2022 23:59
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US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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"/>

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	18 APR 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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"/>

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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°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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 691

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2022 00:01
Patient Cloud Close Date & Time	04 JUL 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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"/>

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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"/>

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

Date and time of submission

Patient Cloud Open Date & Time	18 AUG 2022 00:01
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Patient Cloud Close Date & Time	22 AUG 2022 23:59
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US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
Patient Cloud Close Date & Time	29 AUG 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 ☐

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
Patient Cloud Close Date & Time	26 SEP 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3822003

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:00:59

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		31 MAR 2021 13:54:25

US3822003

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:04:59

Generated On: 10 Jun 2021 10:00:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822003

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:04:59

Generated On: 10 Jun 2021 10:00:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822003

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 19:58:39

Generated On: 10 Jun 2021 10:00:59

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3822003

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 19:58:39

Generated On: 10 Jun 2021 10:00:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822003

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 19:58:39

Generated On: 10 Jun 2021 10:00:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822003

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 19:58:39

Generated On: 10 Jun 2021 10:00:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822003

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 19:58:39

Generated On: 10 Jun 2021 10:00:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822003

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 19:58:39

Generated On: 10 Jun 2021 10:00:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822003

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 19:58:39

Generated On: 10 Jun 2021 10:00:59

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

Visit date (dd MMM yyyy)	23 FEB 2021
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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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US3822003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 19:58:40

Generated On: 10 Jun 2021 10:00:59

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) _____

US3822003

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 19:58:39

Generated On: 10 Jun 2021 10:00:59

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.

US3822003

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 19:58:39

Generated On: 10 Jun 2021 10:00:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 FEB 2021
Collection time (00:00-23:59)	09:54 (24 HR)
Collection date and time (derived)	23 FEB 2021 09:54

US3822003

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 19:58:39

Generated On: 10 Jun 2021 10:00:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822003

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 11 Apr 2021 23:55:10

Generated On: 10 Jun 2021 10:00:59

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3822003

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 11 Apr 2021 23:55:10

Generated On: 10 Jun 2021 10:00:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822003

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

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

US3822003

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3822003

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:00:59

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"/>

US3822003

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:00:59

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3822003

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 19:58:39

Generated On: 10 Jun 2021 10:00:59

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

Visit date (dd MMM yyyy)	4 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
------------	---------------

US3822003

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

Form: Unblinding

Data signed: (b) (4) 11 Apr 2021 23:55:10

Generated On: 10 Jun 2021 10:00:59

Date of updated informed consent (dd MMM yyyy) 4 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 4 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3822003

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 19:58:39

Generated On: 10 Jun 2021 10:00:59

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

Collection date (dd MMM yyyy)	4 JAN 2021
-------------------------------	------------

Collection time (00:00-23:59)	15:27 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	4 JAN 2021 15:27
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US3822003

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 19:58:39

Generated On: 10 Jun 2021 10:00:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 JAN 2021
Collection time (00:00 - 23:59)	15:57
Collection Date and Time (derived)	4 JAN 2021 15:57

US3822003

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 18:44:29

Generated On: 10 Jun 2021 10:00:59

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 18:44:29

Generated On: 10 Jun 2021 10:00:59

AEID

Adverse event

URTICARIAL RASH (RIGHT
ARM)

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

16 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)

30 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 ☐

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US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 18:44:29

Generated On: 10 Jun 2021 10:00:59

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

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Mar 2021 18:44:29

Generated On: 10 Jun 2021 10:00:59

AEID

Adverse event

EXCESSIVE SALIVA ON SIDE
NASAL SWAB COLLECTED

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)

4 AUG 2020

Start time (00:00-23:59)

11:30 (24 HR)

AE start date and time (derived)

4 AUG 2020 11:30

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

4 AUG 2020

End time (00:00-23:59)

11:50 (24 HR)

AE End Date and Time (derived)

4 AUG 2020 11:50

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 ☐

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US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Mar 2021 18:44:29

Generated On: 10 Jun 2021 10:00:59

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PT WITH SALIVA IN POSTERIOR PHARYNX, ON SIDE OF NASAL SWAB. NO DIFFICULTY SWALLOWING, NO SHORTNESS OF BREATH, NO WHEEZING. NO SWELLING ON EXAM.
Serious Adverse Event Derived (CSA Programming Field Only)	0
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Mar 2021 18:44:29

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Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Mar 2021 18:44:29

Generated On: 10 Jun 2021 10:00:59

AEID	USA-US126-2020-MRNA-1273-P30 1000007
Adverse event	MYOCARDIAL INFARCTION
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)	24 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	27 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	24 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	27 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Mar 2021 18:44:29

Generated On: 10 Jun 2021 10:00:59

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

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Mar 2021 18:44:29

Generated On: 10 Jun 2021 10:00:59

PATIENT PRESENTED TO AN
NEW HANOVER ER 10/24/2020
WITH CHEST PAIN. HE WAS
FOUND TO HAVE AN
ABNORMAL EKG AND
ELEVATED TROPONIN. HE WAS
MONITORED OVER NIGHT AND
HAD A LEFT HEART CATH. HE
HAD A STENT PLACED.

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

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Mar 2021 18:44:29

Generated On: 10 Jun 2021 10:00:59

AEID	
Adverse event	CORONARY ARTERY DISEASE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	24 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Mar 2021 18:44:29

Generated On: 10 Jun 2021 10:00:59

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

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 12 Mar 2021 18:44:29

Generated On: 10 Jun 2021 10:00:59

AEID

Adverse event

CARDIAC CHEST PRESSURE

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 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 NOV 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 (5)

Data signed: (b) (4) 12 Mar 2021 18:44:29

Generated On: 10 Jun 2021 10:00:59

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	THE PATIENT STARTED HAVING CHEST PRESSURE ON 11/10/2020. ON 11/12/2020 IT WAS STILL ONGOING SO THE PATIENT PRESENTED TO THE ER. HE WAS DIAGNOSED WITH ACUTE PERICARDITIS.
Serious Adverse Event Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 12 Mar 2021 18:44:29

Generated On: 10 Jun 2021 10:00:59

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

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 12 Mar 2021 18:44:29

Generated On: 10 Jun 2021 10:00:59

AEID	USA-US126-2020-MRNA-1273-P30 1000008
Adverse event	ACUTE PERICARDITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 NOV 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)	13 NOV 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 type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	12 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	13 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 12 Mar 2021 18:44:29

Generated On: 10 Jun 2021 10:00:59

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

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 12 Mar 2021 18:44:29

Generated On: 10 Jun 2021 10:00:59

THE PATIENT PRESENTED TO
THE ER WITH CHEST PRESSURE
AND WAS ADMITTED. HE WAS
DIAGNOSED WITH ACUTE
PERICARDITIS. AN EKG WAS
COMPLETED AND SHOWED
INCOMPLETE RIGHT BUNDLE
BRANCH BLOCK, LEFT
ANTERIOR FASCICULAR
BLOCK. IT WAS WORSE IN THE
SUPINE POSITION. CHEST
X-RAY SHOWED NO ACUTE
ABNORMALITY.

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

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 19:58:39

Generated On: 10 Jun 2021 10:00:59

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

Yes ☒

No ☐

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

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN,
HEADACHE, SWELLING AT
INJECTION SITE, CHILLS,
FATIGUE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

	Transdermal	<input type="checkbox"/>
	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)	01 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	02 SEP 2020	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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Name of Medication SIMVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

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 (2)

Data signed: (b) (4) 02 Apr 2021 19:58:38

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	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)		03 DEC 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 (3)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS II

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 (3)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 JAN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (4)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

Name of Medication MEDROL PACK

Prophylaxis Yes ☐
No ☒

Indication URTICARIAL RASH (RIGHT ARM)

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 19:58:38

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	16 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

Name of Medication TDAP VACCINE

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 (5)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

	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)		12 APR 2016
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		12 APR 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 (6)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

Name of Medication INFLUENZA

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 (6)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

	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)		16 OCT 2019
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		16 OCT 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 (7)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

Name of Medication INFLUENZA

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 (7)

Data signed: (b) (4) 02 Apr 2021 19:58:38

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	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)	1 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) 1 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 (8)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

Name of Medication PNEUMOCOCCAL

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 (8)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

	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)		10 SEP 2016
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		10 SEP 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 (9)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

Name of Medication ZOSTER RECOMBINANT

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 (9)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

	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)		3 MAR 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		3 MAR 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 (10)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

Name of Medication ZOSTER RECOMBINANT

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 (10)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

	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)		5 DEC 2019
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 5 DEC 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 19:58:38

Generated On: 10 Jun 2021 10:00:59

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION,
CORONARY ARTERY DISEASE

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 19:58:38

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	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)		24 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		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 (12)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

Name of Medication PRASUGREL

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 Apr 2021 19:58:38

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

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION,
CORONARY ARTERY DISEASE

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

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

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION

Dose per administration 2.5

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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US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

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

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

Name of Medication METOPROLOL SUCCINATE

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION,
CORONARY ARTERY DISEASE

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 ☐

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EAB) (1725)

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

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

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

Name of Medication COLCHICINE

Prophylaxis Yes ☐
No ☒

Indication ACUTE PERICARDITIS

Dose per administration 0.6

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

	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)	12 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	13 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication ACUTE PERICARDITIS

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

	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)	12 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	13 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication ACUTE PERICARDITIS

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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US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 02 Apr 2021 19:58:38

Generated On: 10 Jun 2021 10:00:59

	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)	12 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	13 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

US3822003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 19:58:39

Generated On: 10 Jun 2021 10:00:59

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3822003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 19:58:39

Generated On: 10 Jun 2021 10:00:59

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
25 OCT 2020	CARDIAC STENT	Adverse Event	
12 NOV 2020	CARDIAC LAB WORK	Adverse Event	
12 NOV 2020	CHEST X-RAY	Adverse Event	
12 NOV 2020	ECHOCARDIOGRAM	Adverse Event	
24 OCT 2020	HEART CATH	Adverse Event	
18 NOV 2020	ELECTROCARDIOGRAM	Diagnostic	

US3822003

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:00:59

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

US3822003

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:00:59

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 19:58:39

Generated On: 10 Jun 2021 10:00:59

SAEID	USA-US126-2020-MRNA-1273-P301000007
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	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NORTH CAROLINA
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 19:58:39

Generated On: 10 Jun 2021 10:00:59

SAEID	USA-US126-2020-MRNA-1273-P301000007
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	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NORTH CAROLINA
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	29/OCT/2020 13:20
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

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 19:58:39

Generated On: 10 Jun 2021 10:00:59

SAEID	USA-US126-2020-MRNA-1273-P301000007
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	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NORTH CAROLINA
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	30/OCT/2020 08:13
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

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 19:58:39

Generated On: 10 Jun 2021 10:00:59

SAEID	USA-US126-2020-MRNA-1273-P301000007
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	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NORTH CAROLINA
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	15/DEC/2020 16:04
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 19:58:39

Generated On: 10 Jun 2021 10:00:59

SAEID	USA-US126-2020-MRNA-1273-P301000008
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	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 19:58:39

Generated On: 10 Jun 2021 10:00:59

SAEID	USA-US126-2020-MRNA-1273-P301000008
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	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	17/NOV/2020 19:57
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

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 19:58:39

Generated On: 10 Jun 2021 10:00:59

SAEID	USA-US126-2020-MRNA-1273-P301000008
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	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	19/NOV/2020 15:06
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

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 19:58:39

Generated On: 10 Jun 2021 10:00:59

SAEID	USA-US126-2020-MRNA-1273-P301000008
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	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	15/DEC/2020 15:00
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

US3822003 (Prod: Tryon Medical Partners, PLLC)

US3822003

Form: Participant Creation

Generated On: 10 Jun 2021 10:00:59

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:36:04
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 14:35:57
User entered 'US3822003'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 14:54:36

US3822003

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:00:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	04 Aug 2020 15:23:14

US3822003

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 14:54:36

US3822003

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4)	04 Aug 2020 15:23:14

US3822003

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:00:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered 'SCRN'	System	04 Aug 2020 15:23:14

US3822003

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:59

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered (b) (6) 1955'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 14:54:37

US3822003

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:59

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '65'	Kelly Woodell (b) (4)	04 Aug 2020 15:24:08

US3822003

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:59

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered 'YEARS'	System	04 Aug 2020 15:24:08

US3822003

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:59

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered '65'	System	04 Aug 2020 15:31:26

US3822003

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:59

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Male (M)'	Kelly Woodell (b) (4)	04 Aug 2020 15:24:08

US3822003

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:59

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kelly Woodell (b) (4)	04 Aug 2020 15:24:08

US3822003

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:59

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'I'	Kelly Woodell (b) (4)	04 Aug 2020 15:24:08

US3822003

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:59

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '0'	Kelly Woodell (b) (4)	04 Aug 2020 15:24:08

US3822003

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:59

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '0'	Kelly Woodell (b) (4)	04 Aug 2020 15:24:08

US3822003

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:59

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '0'	Kelly Woodell (b) (4)	04 Aug 2020 15:24:08

US3822003

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:59

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '0'	Kelly Woodell (b) (4)	04 Aug 2020 15:24:08

US3822003

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '0'	Kelly Woodell (b) (4)	04 Aug 2020 15:24:08

US3822003

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:59

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered empty.	Kelly Woodell (b) (4)	04 Aug 2020 15:24:08

US3822003

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:59

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '0'	Kelly Woodell (b) (4)	04 Aug 2020 15:24:08

US3822003

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:59

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '0'	Kelly Woodell (b) (4)	04 Aug 2020 15:24:08

US3822003

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:59

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '04 Aug 2020'	Kelly Woodell (b) (4)	04 Aug 2020 15:31:26

US3822003

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered 'Aug 2020'	System	04 Aug 2020 15:31:26

US3822003

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered '2020'	System	04 Aug 2020 15:31:26

US3822003

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:59

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Amendment 1 (1)'	Kelly Woodell (b) (4)	04 Aug 2020 15:31:26

US3822003

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	04 Aug 2020 15:31:26

US3822003

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:59

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered empty.	Kelly Woodell (b) (4)	04 Aug 2020 15:31:26

US3822003

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:59

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered empty.	Kelly Woodell (b) (4)	04 Aug 2020 15:31:26

US3822003

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:59

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'No (N)'	Kelly Woodell (b) (4)	04 Aug 2020 15:31:26

US3822003

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:59

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 14:54:36

US3822003

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:59

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered 'I'	System	04 Aug 2020 15:31:34

US3822003

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	04 Aug 2020 15:31:34

US3822003

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:00:59

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	05 Aug 2020 18:59:39

US3822003

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
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) (4), (b) (6)	29 Sep 2020 11:56:32
' (Site from DM).		
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 15:03:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 15:03:49
Data point term sent to Coder	System	28 Sep 2020 15:02:40
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) (b) (4)	28 Sep 2020 15:02:12
' answered with 'KS: Please see Metformin has been listed for this medical history. condition term updated. ' (Site from DM).		
Coding entries removed.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:02:06
User entered 'DIABETES MELLITUS TYPE II' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:02:06
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 09:18:39
' (Site from DM).		

US3822003

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:59

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 19:00:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 19:00:59
Data point term sent to Coder	System	05 Aug 2020 19:00:37
User entered 'Diabetes Type II'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 19:00:09

US3822003

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'UN Jan 2020'	Kelly Woodell (b) (4)	05 Aug 2020 19:00:09

US3822003

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '0'	Kelly Woodell (b) (4)	05 Aug 2020 19:00:09

US3822003

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	05 Aug 2020 19:00:09

US3822003

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered empty.	Kelly Woodell (b) (4)	05 Aug 2020 19:00:09

US3822003

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '0'	Kelly Woodell (b) (4)	05 Aug 2020 19:00:09

US3822003

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered 'Jan 2020'	System	05 Aug 2020 19:00:09

US3822003

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered '2020'	System	05 Aug 2020 19:00:09

US3822003

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered empty.	System	05 Aug 2020 19:00:09

US3822003

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered empty.	System	05 Aug 2020 19:00:09

US3822003

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit/hyperactivity disorder - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 12:49:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 12:49:08
Data point term sent to Coder	System	05 Aug 2020 19:01:40
User entered 'Attention Deficient Hyperactivity Disorder'	Kelly Woodell (b) (4)	05 Aug 2020 19:00:52

US3822003

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'UN UNK 1990'	Kelly Woodell (b) (4)	05 Aug 2020 19:00:52

US3822003

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:59

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	(b) (4)	
User entered '0' reason for change: Data Entry Error	System	13 Aug 2020 21:40:16
User entered '0' reason for change: Data Entry Error	Kelly Woodell (b) (4)	13 Aug 2020 21:40:16
User opened query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	(b) (4)	
User entered '1'	System	05 Aug 2020 19:00:52
	Kelly Woodell (b) (4)	05 Aug 2020 19:00:52
	(b) (4)	

US3822003

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
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	13 Aug 2020 21:40:16
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelly Woodell (b) (4)	13 Aug 2020 21:40:16
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	05 Aug 2020 19:00:52
	Kelly Woodell (b) (4)	05 Aug 2020 19:00:52
	(b) (4)	

US3822003

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered empty.	Kelly Woodell (b) (4)	05 Aug 2020 19:00:52

US3822003

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '0'	Kelly Woodell (b) (4)	05 Aug 2020 19:00:52

US3822003

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered 'Jan 1990'	System	05 Aug 2020 19:00:52

US3822003

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered '1990'	System	05 Aug 2020 19:00:52

US3822003

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered empty.	System	05 Aug 2020 19:00:52

US3822003

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered empty.	System	05 Aug 2020 19:00:52

US3822003

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User closed query 'Per CDM re-query: Site response is noted that information will be updated on 10/27 during Day 85 PC. However, this information was not updated. Please update to verify the location of MH#3. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 15:21:27
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis contact, LLT: Contact dermatitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:54:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:54:58
Data point term sent to Coder	System	24 Nov 2020 18:26:28
Query 'Per CDM re-query: Site response is noted that information will be updated on 10/27 during Day 85 PC. However, this information was not updated. Please update to verify the location of MH#3. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 18:25:59
Coding entries removed.	(b) (4), (b) (6)	24 Nov 2020 18:25:54
User entered 'CONTACT DERMATATIS - Sea life, snorkling' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 18:25:54
User opened query 'Per CDM re-query: Site response is noted that information will be updated on 10/27 during Day 85 PC. However, this information was not updated. Please update to verify the location of MH#3. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 15:49:31
User closed query 'Per CDM: Please verify the location of MH#3 with the patient during Safety Call Day 85 and update the information once known. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 15:49:31
Query 'Per CDM: Please verify the location of MH#3 with the patient during Safety Call Day 85 and update the information once known. Thank you.' answered with 'Dat 85 PC scheduled for 10/27 and information will be updated at that time.' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	15 Oct 2020 16:05:58

US3822003

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:59

Condition

Audit	User	Time (GMT)
User opened query 'Per CDM: Please verify the location of MH#3 with the patient during Safety Call Day 85 and update the information once known. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 12:21:20
User closed query 'Per DM CLR: Please specify the location of CONTACT DERMATATIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 11:34:52
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis contact, LLT: Contact dermatitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 07:20:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 07:20:44
Data point term sent to Coder	System	28 Sep 2020 15:05:44
Query 'Per DM CLR: Please specify the location of CONTACT DERMATATIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'undated' (Site from DM).	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:05:36
Coding entries removed.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:05:26
User entered 'CONTACT DERMATATIS (location unknown)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:05:26
User opened query 'Per DM CLR: Please specify the location of CONTACT DERMATATIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 09:18:47
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis contact, LLT: Contact dermatitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 07:45:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 07:45:11
Data point term sent to Coder	System	05 Aug 2020 19:01:40

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:59

[Condition](#)

Audit	User	Time (GMT)
User entered 'Contact Dermatatis'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 19:01:19

US3822003

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '02 Jul 2020'	Kelly Woodell (b) (4)	05 Aug 2020 19:01:19

US3822003

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:59

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	(b) (4)	
User entered '0' reason for change: Data Entry Error	System	13 Aug 2020 21:40:26
User entered '0' reason for change: Data Entry Error	Kelly Woodell (b) (4)	13 Aug 2020 21:40:26
User opened query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	(b) (4)	
User entered '1'	System	05 Aug 2020 19:01:19
	Kelly Woodell (b) (4)	05 Aug 2020 19:01:19
	(b) (4)	

US3822003

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:25:54
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 21:40:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 21:40:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	13 Aug 2020 21:40:26
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 19:01:19
User entered empty.	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 19:01:19

US3822003

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '9 Jul 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:25:54
User entered empty.	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 19:01:19

US3822003

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '0'	Kelly Woodell (b) (4)	05 Aug 2020 19:01:19

US3822003

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered 'Jul 2020'	System	05 Aug 2020 19:01:19

US3822003

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered '2020'	System	05 Aug 2020 19:01:19

US3822003

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered 'Jul 2020'	System	24 Nov 2020 18:25:54
User entered empty.	System	05 Aug 2020 19:01:19

US3822003

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered '2020'	System	24 Nov 2020 18:25:54
User entered empty.	System	05 Aug 2020 19:01:19

US3822003

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Synovial and bursal disorders, HLT: Bursal disorders, PT: Bursitis, LLT: Olecranon bursitis - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 21:26:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 21:26:04
Data point term sent to Coder	System	05 Aug 2020 19:02:41
User entered 'Bursitis of olecranon of right elbow'	Kelly Woodell (b) (4)	05 Aug 2020 19:01:48

US3822003

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '07 May 2020'	Kelly Woodell (b) (4)	05 Aug 2020 19:01:48

US3822003

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '0'	Kelly Woodell (b) (4)	05 Aug 2020 19:01:48

US3822003

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	05 Aug 2020 19:01:48

US3822003

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered empty.	Kelly Woodell (b) (4)	05 Aug 2020 19:01:48

US3822003

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '0'	Kelly Woodell (b) (4)	05 Aug 2020 19:01:48

US3822003

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered 'May 2020'	System	05 Aug 2020 19:01:48

US3822003

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered '2020'	System	05 Aug 2020 19:01:48

US3822003

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered empty.	System	05 Aug 2020 19:01:48

US3822003

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered empty.	System	05 Aug 2020 19:01:48

US3822003

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
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 hypertrophy - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 12:47:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 12:47:20
Data point term sent to Coder	System	05 Aug 2020 19:02:45
User entered 'Benign Prostatic Hypertrophy with outflow obstruction'	Kelly Woodell (b) (4)	05 Aug 2020 19:02:19

US3822003

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '17 Jul 2020'	Kelly Woodell (b) (4)	05 Aug 2020 19:02:19

US3822003

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '0'	Kelly Woodell (b) (4)	05 Aug 2020 19:02:19

US3822003

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	05 Aug 2020 19:02:19

US3822003

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered empty.	Kelly Woodell (b) (4)	05 Aug 2020 19:02:19

US3822003

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '0'	Kelly Woodell (b) (4)	05 Aug 2020 19:02:19

US3822003

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered 'Jul 2020'	System	05 Aug 2020 19:02:19

US3822003

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered '2020'	System	05 Aug 2020 19:02:19

US3822003

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered empty.	System	05 Aug 2020 19:02:19

US3822003

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered empty.	System	05 Aug 2020 19:02:19

US3822003

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Hiatal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 19:04:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 19:04:04
Data point term sent to Coder	System	05 Aug 2020 19:02:47
User entered 'Hiatal Hernia'	Kelly Woodell (b) (4)	05 Aug 2020 19:02:40

US3822003

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '17 Jul 2019'	Kelly Woodell (b) (4)	05 Aug 2020 19:02:40

US3822003

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '0'	Kelly Woodell (b) (4)	05 Aug 2020 19:02:40

US3822003

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	05 Aug 2020 19:02:40

US3822003

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered empty.	Kelly Woodell (b) (4)	05 Aug 2020 19:02:40

US3822003

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '0'	Kelly Woodell (b) (4)	05 Aug 2020 19:02:40

US3822003

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered 'Jul 2019'	System	05 Aug 2020 19:02:40

US3822003

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered '2019'	System	05 Aug 2020 19:02:40

US3822003

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered empty.	System	05 Aug 2020 19:02:40

US3822003

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered empty.	System	05 Aug 2020 19:02:40

US3822003

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 19:05:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 19:05:03
Data point term sent to Coder	System	05 Aug 2020 19:03:48
User entered 'Hypercholesterolemia'	Kelly Woodell (b) (4)	05 Aug 2020 19:03:04

US3822003

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'UN UNK 2017'	Kelly Woodell (b) (4)	05 Aug 2020 19:03:04

US3822003

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '0'	Kelly Woodell (b) (4)	05 Aug 2020 19:03:04

US3822003

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	05 Aug 2020 19:03:04

US3822003

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered empty.	Kelly Woodell (b) (4)	05 Aug 2020 19:03:04

US3822003

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '0'	Kelly Woodell (b) (4)	05 Aug 2020 19:03:04

US3822003

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered 'Jan 2017'	System	05 Aug 2020 19:03:04

US3822003

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered '2017'	System	05 Aug 2020 19:03:04

US3822003

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered empty.	System	05 Aug 2020 19:03:04

US3822003

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered empty.	System	05 Aug 2020 19:03:04

US3822003

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 19:05:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 19:05:02
Data point term sent to Coder	System	05 Aug 2020 19:03:48
User entered 'Gastroesophageal Reflux Disease'	Kelly Woodell (b) (4)	05 Aug 2020 19:03:29

US3822003

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '08 Jan 2019'	Kelly Woodell (b) (4)	05 Aug 2020 19:03:29

US3822003

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '0'	Kelly Woodell (b) (4)	05 Aug 2020 19:03:29

US3822003

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	05 Aug 2020 19:03:29

US3822003

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered empty.	Kelly Woodell (b) (4)	05 Aug 2020 19:03:29

US3822003

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '0'	Kelly Woodell (b) (4)	05 Aug 2020 19:03:29

US3822003

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered 'Jan 2019'	System	05 Aug 2020 19:03:29

US3822003

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered '2019'	System	05 Aug 2020 19:03:29

US3822003

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered empty.	System	05 Aug 2020 19:03:29

US3822003

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered empty.	System	05 Aug 2020 19:03:29

US3822003

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	05 Aug 2020 18:09:48

US3822003

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '04 Aug 2020'	Kelly Woodell (b) (4)	05 Aug 2020 18:09:48

US3822003

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '11:50'	Kelly Woodell (b) (4)	05 Aug 2020 18:09:48

US3822003

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered '04 Aug 2020 11:50'	System	05 Aug 2020 18:09:48

US3822003

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User closed query 'Per CDM: Please recheck Height and Weight and update accordingly' (Site from DM).	(b) (4)	
Query 'Per CDM: Please recheck Height and Weight and update accordingly' answered with 'Height updated' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 16:49:26
Query 'Per CDM: Please recheck Height and Weight and update accordingly' answered with 'Height updated' (Site from DM).	Kelly Woodell (b) (4)	26 Aug 2020 01:14:04
User entered '63' in reason for change: Data Entry Error	(b) (4)	
User opened query 'Per CDM: Please recheck Height and Weight and update accordingly' (Site from DM).	Kelly Woodell (b) (4)	26 Aug 2020 01:13:54
User entered '160' in	(b) (4)	
DataPoint set to visible.	(b) (4), (b) (6)	22 Aug 2020 20:59:56
	Kelly Woodell (b) (4)	05 Aug 2020 18:09:48
	(b) (4)	
	System	04 Aug 2020 15:31:34

US3822003

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '187' lb	Kelly Woodell (b) (4)	05 Aug 2020 18:09:48
DataPoint set to visible.	System	04 Aug 2020 15:31:34

US3822003

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
Amendment Manager: User entered '33.19483'	System	16 Sep 2020 23:42:20
User entered '33.2'	System	26 Aug 2020 01:13:54
User entered '5.1'	System	05 Aug 2020 18:09:48
DataPoint set to visible.	System	04 Aug 2020 15:31:34

US3822003

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered 'kg/m2'	System	05 Aug 2020 18:09:48
DataPoint set to visible.	System	04 Aug 2020 15:31:34

US3822003

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User closed query 'Per CDM: Re-query: ND (Not done) noted for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP, however, please also keep the Units blank for all the data-fields. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 11:57:46
Query 'Per CDM: Re-query: ND (Not done) noted for Krishna Shah PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP, however, please also keep the Units blank for all the data-fields. Thank you.' answered with 'updated ' (Site from DM).	(b) (4) (b) (4)	28 Sep 2020 15:07:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:06:56
User opened query 'Per CDM: Re-query: ND (Not done) noted for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP, however, please also keep the Units blank for all the data-fields. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 07:51:50
User closed query 'Per CDM: Site response is noted; however, the fields were not updated to 'ND' as previous query stated. Please update temperature, pulse, respiratory rate, systolic BP, and diastolic BP ALL as 'ND'. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 07:51:50
Query 'Per CDM: Site response is noted; however, the fields were not updated to 'ND' as previous query stated. Please update temperature, pulse, respiratory rate, systolic BP, and diastolic BP ALL as 'ND'. ' answered with 'data updated per query' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:24:46
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:24:35
User opened query 'Per CDM: Site response is noted; however, the fields were not updated to 'ND' as previous query stated. Please update temperature, pulse, respiratory rate, systolic BP, and diastolic BP ALL as 'ND'. ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 16:51:17

US3822003

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 16:51:17
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'Temperature is correct as is' (Site from DM).	Kelly Woodell (b) (4)	26 Aug 2020 01:14:29
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 20:59:33
User entered '97.3' F	Kelly Woodell (b) (4)	05 Aug 2020 18:09:48

US3822003

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered empty; reason for change Data Entry Error	Krishna Shah (b) (4)	28 Oct 2020 17:56:08
User entered 'Oral (Oral)'	Kelly Woodell (b) (4)	05 Aug 2020 18:09:48

US3822003

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered empty.	Kelly Woodell (b) (4)	05 Aug 2020 18:09:48

US3822003

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	16 Sep 2020 22:24:35
User entered '59'	Kelly Woodell (b) (4)	05 Aug 2020 18:09:48
	(b) (4)	

US3822003

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered 'bpm'	System	05 Aug 2020 18:09:48

US3822003

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	16 Sep 2020 22:24:35
User entered '10'	Kelly Woodell (b) (4)	05 Aug 2020 18:09:48
	(b) (4)	

US3822003

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered 'breaths/min'	System	05 Aug 2020 18:09:48

US3822003

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	16 Sep 2020 22:24:35
User entered '145'	Kelly Woodell (b) (4)	05 Aug 2020 18:09:48

US3822003

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered 'mmHg'	System	05 Aug 2020 18:09:48

US3822003

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	16 Sep 2020 22:24:35
User entered '97'	Kelly Woodell (b) (4)	05 Aug 2020 18:09:48
	(b) (4)	

US3822003

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User entered 'mmHg'	System	05 Aug 2020 18:09:48

US3822003

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57

US3822003

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57

US3822003

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	05 Aug 2020 18:09:59

US3822003

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '04 Aug 2020'	Kelly Woodell (b) (4)	05 Aug 2020 18:09:59

US3822003

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'No (N)'	Kelly Woodell (b) (4)	05 Aug 2020 18:11:25

US3822003

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'No (N)'	Kelly Woodell (b) (4)	05 Aug 2020 18:11:25

US3822003

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:59

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'No (N)'	Kelly Woodell (b) (4)	05 Aug 2020 18:11:25

US3822003

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:59

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'No (N)'	Kelly Woodell (b) (4)	05 Aug 2020 18:11:25

US3822003

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:59

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'No (N)'	Kelly Woodell (b) (4)	05 Aug 2020 18:11:25

US3822003

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:59

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'No (N)'	Kelly Woodell (b) (4)	05 Aug 2020 18:11:25

US3822003

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:59

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'No (N)'	Kelly Woodell (b) (4)	05 Aug 2020 18:11:25

US3822003

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:59

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'No (N)'	Kelly Woodell (b) (4)	05 Aug 2020 18:11:25

US3822003

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:59

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'No (N)'	Kelly Woodell (b) (4)	05 Aug 2020 18:11:25

US3822003

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:59

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'No (N)'	Kelly Woodell (b) (4)	05 Aug 2020 18:11:25

US3822003

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:59

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'No (N)'	Kelly Woodell (b) (4)	05 Aug 2020 18:11:25

US3822003

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'No (N)'	Kelly Woodell (b) (4)	05 Aug 2020 18:11:25

US3822003

Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered empty.	Kelly Woodell (b) (4)	05 Aug 2020 18:11:25

US3822003

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:59

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'I'	Kelly Woodell (b) (4)	05 Aug 2020 18:11:25

US3822003

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:59

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '0'	Kelly Woodell (b) (4)	05 Aug 2020 18:11:25

US3822003

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '0'	Kelly Woodell (b) (4)	05 Aug 2020 18:11:25

US3822003

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:59

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '0'	Kelly Woodell (b) (4)	05 Aug 2020 18:11:25

US3822003

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:59

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '0'	Kelly Woodell (b) (4)	05 Aug 2020 18:11:25

US3822003

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '0'	Kelly Woodell (b) (4)	05 Aug 2020 18:11:25

US3822003

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '0'	Kelly Woodell (b) (4)	05 Aug 2020 18:11:25

US3822003

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:26:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered empty.	Kelly Woodell (b) (4)	05 Aug 2020 18:11:25

US3822003

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:00:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	05 Aug 2020 18:11:46

US3822003

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:00:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '04 Aug 2020'	Kelly Woodell (b) (4)	05 Aug 2020 18:11:46

US3822003

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:00:59

[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 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4)	05 Aug 2020 18:11:46

US3822003

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:00:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'VISIT1'	System	05 Aug 2020 18:11:46

US3822003

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 14:59:30

US3822003

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:59

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 01:56:03
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:56:03
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Aug 2020 14:59:30
User entered '184619' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 14:59:30

US3822003

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 14:59:30

US3822003

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:59

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 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
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	04 Aug 2020 15:34:48
User entered 'No (N)' reason for change: Data Entry Error	System	04 Aug 2020 15:34:48
User opened query 'Data is required. Please complete.' (Site from System).	Kelly Woodell (b) (4)	04 Aug 2020 15:34:48
User entered empty.	(b) (4)	
	System	04 Aug 2020 15:34:40
	Kelly Woodell (b) (4)	04 Aug 2020 15:34:40
	(b) (4)	

US3822003

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:59

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 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
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	04 Aug 2020 15:34:48
User entered 'No (N)' reason for change: Data Entry Error	System	04 Aug 2020 15:34:48
User opened query 'Data is required. Please complete.' (Site from System).	Kelly Woodell (b) (4)	04 Aug 2020 15:34:48
User entered empty.	(b) (4)	
	System	04 Aug 2020 15:34:40
	Kelly Woodell (b) (4)	04 Aug 2020 15:34:40
	(b) (4)	

US3822003

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
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	04 Aug 2020 15:34:48
User entered 'No (N)' reason for change: Data Entry Error	System	04 Aug 2020 15:34:48
User opened query 'Data is required. Please complete.' (Site from System).	Kelly Woodell (b) (4)	04 Aug 2020 15:34:48
User entered empty.	(b) (4)	
	System	04 Aug 2020 15:34:40
	Kelly Woodell (b) (4)	04 Aug 2020 15:34:40
	(b) (4)	

US3822003

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:59

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
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	04 Aug 2020 15:34:48
User entered 'No (N)' reason for change: Data Entry Error	System	04 Aug 2020 15:34:48
User opened query 'Data is required. Please complete.' (Site from System).	Kelly Woodell (b) (4)	04 Aug 2020 15:34:48
User entered empty.	(b) (4)	
	System	04 Aug 2020 15:34:40
	Kelly Woodell (b) (4)	04 Aug 2020 15:34:40
	(b) (4)	

US3822003

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:59

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
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	04 Aug 2020 15:34:48
User entered 'No (N)' reason for change: Data Entry Error	System	04 Aug 2020 15:34:48
User opened query 'Data is required. Please complete.' (Site from System).	Kelly Woodell (b) (4)	04 Aug 2020 15:34:48
User entered empty.	(b) (4)	
	System	04 Aug 2020 15:34:40
	Kelly Woodell (b) (4)	04 Aug 2020 15:34:40
	(b) (4)	

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User closed query 'Per CDM: Response is noted; however, the height and weight should be recorded as 'ND' for this section according to the CCGs pages 15-16. Please update both the height and weight as 'ND'. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 05:30:37
Query 'Per CDM: Response is noted; however, the height and weight should be recorded as 'ND' for this section according to the CCGs pages 15-16. Please update both the height and weight as 'ND'. ' answered with 'data updated per query' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:26:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:26:11
User opened query 'Per CDM: Response is noted; however, the height and weight should be recorded as 'ND' for this section according to the CCGs pages 15-16. Please update both the height and weight as 'ND'. ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 16:35:25
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 16:35:25
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with '63 inches is correct as is' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	26 Aug 2020 01:16:32
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 21:00:24
User entered '63' in	Kelly Woodell (b) (4) (b) (4)	13 Aug 2020 21:37:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:59

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	16 Sep 2020 22:26:11
User entered '187' lb	Kelly Woodell (b) (4)	13 Aug 2020 21:37:29
	(b) (4)	

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User closed query 'Per CDM: Response is noted; however, the height and weight should be recorded as 'ND' for this section according to the CCGs pages 15-16. Please update both the height and weight as 'ND'. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 05:30:37
Query 'Per CDM: Response is noted; however, the height and weight should be recorded as 'ND' for this section according to the CCGs pages 15-16. Please update both the height and weight as 'ND'. ' answered with 'data updated per query' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:26:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:26:11
User opened query 'Per CDM: Response is noted; however, the height and weight should be recorded as 'ND' for this section according to the CCGs pages 15-16. Please update both the height and weight as 'ND'. ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 16:35:25
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 16:35:25
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with '63 inches is correct as is' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	26 Aug 2020 01:16:32
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 21:00:24
User entered '63' in	Kelly Woodell (b) (4) (b) (4)	13 Aug 2020 21:37:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

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[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	16 Sep 2020 22:26:11
User entered '187' lb	Kelly Woodell (b) (4)	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User accepted default value 'Pre-Dose (PREDOSE)'	Kelly Woodell (b) (4)	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	13 Aug 2020 21:37:56
User entered '04 Aug 2020' reason for change: Data Entry Error	Kelly Woodell (b) (4)	13 Aug 2020 21:37:56
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	13 Aug 2020 21:37:29
User entered '05 Aug 2020'	System	13 Aug 2020 21:37:29
	Kelly Woodell (b) (4)	13 Aug 2020 21:37:29
	(b) (4)	

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	
	System	13 Aug 2020 21:37:56
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	13 Aug 2020 21:37:29
User entered '10:53'	Kelly Woodell (b) (4)	13 Aug 2020 21:37:29
	(b) (4)	

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered '04 Aug 2020 10:53'	System	13 Aug 2020 21:37:56
User entered '05 Aug 2020 10:53'	System	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '97.3' F	Kelly Woodell (b) (4)	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Oral (Oral)'	Kelly Woodell (b) (4)	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered empty.	Kelly Woodell (b) (4)	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '54'	Kelly Woodell (b) (4)	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'bpm'	System	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '14'	Kelly Woodell (b) (4)	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'breaths/min'	System	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '145'	Kelly Woodell (b) (4)	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'mmHg'	System	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '77'	Kelly Woodell (b) (4)	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'mmHg'	System	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User closed query 'Per CDM: Response is noted; however, the height and weight should be recorded as 'ND' for this section according to the CCGs pages 15-16. Please update both the height and weight as 'ND'. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 05:30:37
Query 'Per CDM: Response is noted; however, the height and weight should be recorded as 'ND' for this section according to the CCGs pages 15-16. Please update both the height and weight as 'ND'. ' answered with 'data updated per query' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:26:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:26:11
User opened query 'Per CDM: Response is noted; however, the height and weight should be recorded as 'ND' for this section according to the CCGs pages 15-16. Please update both the height and weight as 'ND'. ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 16:35:25
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 16:35:25
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with '63 inches is correct as is' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	26 Aug 2020 01:16:32
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 21:00:24
User entered '63' in	Kelly Woodell (b) (4) (b) (4)	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:59

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	16 Sep 2020 22:26:11
User entered '187' lb	Kelly Woodell (b) (4)	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User accepted default value 'Post-Dose (POSTDOSE)'	Kelly Woodell (b) (4) (b) (4)	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	13 Aug 2020 21:37:56
User entered '04 Aug 2020' reason for change: Data Entry Error	Kelly Woodell (b) (4)	13 Aug 2020 21:37:56
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	13 Aug 2020 21:37:29
User entered '05 Aug 2020'	System	13 Aug 2020 21:37:29
	Kelly Woodell (b) (4)	13 Aug 2020 21:37:29
	(b) (4)	

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User closed query 'Per CDM: Site response noted, however, please note that Vital Signs were taken 26 minutes after Dose Time. The treatment time on the Exposure CRF is 11:24. The Vital Signs Post Dose Time of Assessment is 11:50. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 06:02:26
Query 'Per CDM: Site response noted, however, please note that Vital Signs were taken 26 minutes after Dose Time. The treatment time on the Exposure CRF is 11:24. The Vital Signs Post Dose Time of Assessment is 11:50. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed. Thanks.' answered with 'Subject had to leave due to personal reasons and could not wait the extra 4 minutes' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	26 Aug 2020 01:19:04
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 14:30:02
User opened query 'Per CDM: Site response noted, however, please note that Vital Signs were taken 26 minutes after Dose Time. The treatment time on the Exposure CRF is 11:24. The Vital Signs Post Dose Time of Assessment is 11:50. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed. Thanks.' (Site from DM).	(b) (4), (b) (6)	14 Aug 2020 14:29:15
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Vitals signs were collected 30 mins post dose per protocol' (Site from System).	Kelly Woodell (b) (4) (b) (4)	13 Aug 2020 21:38:33

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
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).		13 Aug 2020 21:37:56
User entered '11:50'	Kelly Woodell (b) (4) (b) (4)	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered '04 Aug 2020 11:50'	System	13 Aug 2020 21:37:56
User entered '05 Aug 2020 11:50'	System	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '97.3' F	Kelly Woodell (b) (4)	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Oral (Oral)'	Kelly Woodell (b) (4)	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered empty.	Kelly Woodell (b) (4)	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '59'	Kelly Woodell (b) (4)	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'bpm'	System	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '10'	Kelly Woodell (b) (4)	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'breaths/min'	System	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '145'	Kelly Woodell (b) (4)	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'mmHg'	System	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '97'	Kelly Woodell (b) (4)	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'mmHg'	System	13 Aug 2020 21:37:29

US3822003

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:59

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User closed query 'Per CDM: Response is noted; however since the screening and visit 1 day 1 were conducted on the same day, the physical exam field ONLY needs to be marked as 'yes' under the SCREENING FOLDER per CCGs. Please update this record field as 'NO' and remove the date. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 10:17:37
Query 'Per CDM: Response is noted; however since the screening and visit 1 day 1 were conducted on the same day, the physical exam field ONLY needs to be marked as 'yes' under the SCREENING FOLDER per CCGs. Please update this record field as 'NO' and remove the date. ' answered with 'data updated per query' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:25:52
User entered 'No (N)' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:25:34
User opened query 'Per CDM: Response is noted; however since the screening and visit 1 day 1 were conducted on the same day, the physical exam field ONLY needs to be marked as 'yes' under the SCREENING FOLDER per CCGs. Please update this record field as 'NO' and remove the date. ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 16:56:01
User closed query 'Per CDM; per pages 15-16 of the CCGs, please record this as NO and remove date' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 16:56:01
Query 'Per CDM; per pages 15-16 of the CCGs, please record this as NO and remove date' answered with 'Physical exam was completed therefore data is correct' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	26 Aug 2020 01:15:55
User opened query 'Per CDM; per pages 15-16 of the CCGs, please record this as NO and remove date' (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 21:00:55
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	13 Aug 2020 21:38:46

US3822003

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered empty; reason for change Data Entry Error	Kelly Woodell (b) (4)	16 Sep 2020 22:25:34
User entered '04 Aug 2020'	Kelly Woodell (b) (4)	13 Aug 2020 21:38:46

US3822003

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	04 Aug 2020 15:35:22

US3822003

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:59

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered empty.	Kelly Woodell (b) (4)	04 Aug 2020 15:35:22

US3822003

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:59

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 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered empty.	Kelly Woodell (b) (4)	04 Aug 2020 15:35:22

US3822003

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 15:35:22

US3822003

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '04 Aug 2020'	Kelly Woodell (b) (4)	04 Aug 2020 15:35:22

US3822003

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '11:24'	Kelly Woodell (b) (4)	04 Aug 2020 15:35:22

US3822003

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered '04 Aug 2020 11:24'	System	04 Aug 2020 15:35:22

US3822003

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Left Arm (LEFT ARM)'	Kelly Woodell (b) (4)	04 Aug 2020 15:35:22

US3822003

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:59

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'ONCE'	System	04 Aug 2020 15:35:22

US3822003

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 15:35:22

US3822003

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	13 Aug 2020 21:39:08

US3822003

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '04 Aug 2020'	Kelly Woodell (b) (4)	13 Aug 2020 21:39:08

US3822003

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '11:04'	Kelly Woodell (b) (4)	13 Aug 2020 21:39:08

US3822003

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered '04 Aug 2020 11:04'	System	13 Aug 2020 21:39:08

US3822003

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:00:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '04 Aug 2020'	Kelly Woodell (b) (4)	13 Aug 2020 21:39:36

US3822003

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelly Woodell (b) (4)	13 Aug 2020 21:39:36

US3822003

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	13 Aug 2020 21:39:36

US3822003

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '11:10'	Kelly Woodell (b) (4)	13 Aug 2020 21:39:36

US3822003

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered '04 Aug 2020 11:10'	System	13 Aug 2020 21:39:36

US3822003

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelly Woodell (b) (4)	13 Aug 2020 21:39:36

US3822003

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'No (N)'	Kelly Woodell (b) (4)	13 Aug 2020 21:39:36

US3822003

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered empty.	Kelly Woodell (b) (4)	13 Aug 2020 21:39:36

US3822003

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered empty.	System	13 Aug 2020 21:39:36

US3822003

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	13 Aug 2020 21:39:40

US3822003

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'I'	System	13 Aug 2020 21:39:40

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-04T12:02:49', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '47f52254-43a3-4b80-bac9-afb3b718e1be' User entered 'Yes (Y)'	System	04 Aug 2020 16:03:18
	System	04 Aug 2020 16:03:18

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-04T12:02:57', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '47f52254-43a3-4b80-bac9-afb3b718e1be' User entered '97.3'	System	04 Aug 2020 16:03:18
	System	04 Aug 2020 16:03:18

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-04T12:03:05', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '47f52254-43a3-4b80-bac9-afb3b718e1be' User entered 'No (N)'	System	04 Aug 2020 16:03:18
	System	04 Aug 2020 16:03:18

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-04T12:03:14', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '47f52254-43a3-4b80-bac9-afb3b718e1be' User entered '04 Aug 2020 12:03'	System	04 Aug 2020 16:03:18
	System	04 Aug 2020 16:03:18

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '04 Aug 2020 11:44'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '04 Aug 2020 14:14'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-05T09:30:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'cc559b57-efd3-4549-98a1-fd8a0e79a121' User entered 'Yes (Y)'	System	05 Aug 2020 13:30:30
	System	05 Aug 2020 13:30:30

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-05T09:30:06', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'cc559b57-efd3-4549-98a1-fd8a0e79a121' User entered '97.3'	System	05 Aug 2020 13:30:30
	System	05 Aug 2020 13:30:30

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-05T09:30:14', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'cc559b57-efd3-4549-98a1-fd8a0e79a121'	System	05 Aug 2020 13:30:30
User entered 'No (N)'	System	05 Aug 2020 13:30:30

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-05T09:30:29', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'cc559b57-efd3-4549-98a1-fd8a0e79a121'	System	05 Aug 2020 13:30:30
User entered '05 Aug 2020 09:30'	System	05 Aug 2020 13:30:30

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '04 Aug 2020 15:09'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 2'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T09:22:35', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '3865f48a-9ac6-4c67-a8b7-f215da73b830' User entered 'Yes (Y)'	System	06 Aug 2020 13:22:50
	System	06 Aug 2020 13:22:50

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T09:22:40', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '3865f48a-9ac6-4c67-a8b7-f215da73b830' User entered '97.3'	System	06 Aug 2020 13:22:50
	System	06 Aug 2020 13:22:50

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T09:22:44', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '3865f48a-9ac6-4c67-a8b7-f215da73b830'	System	06 Aug 2020 13:22:50
User entered 'No (N)'	System	06 Aug 2020 13:22:50

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T09:22:49', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '3865f48a-9ac6-4c67-a8b7-f215da73b830' User entered '06 Aug 2020 09:22'	System	06 Aug 2020 13:22:50
	System	06 Aug 2020 13:22:50

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 3'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T17:00:08', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'd2bf018d-98e2-492e-ab07-0eca48462405' User entered 'Yes (Y)'	System	06 Aug 2020 21:00:25
	System	06 Aug 2020 21:00:25

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T17:00:13', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'd2bf018d-98e2-492e-ab07-0eca48462405' User entered '98.2'	System	06 Aug 2020 21:00:25
	System	06 Aug 2020 21:00:25

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T17:00:16', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'd2bf018d-98e2-492e-ab07-0eca48462405'	System	06 Aug 2020 21:00:25
User entered 'No (N)'	System	06 Aug 2020 21:00:25

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T17:00:22', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'd2bf018d-98e2-492e-ab07-0eca48462405'	System	06 Aug 2020 21:00:25
User entered '06 Aug 2020 17:00'	System	06 Aug 2020 21:00:25

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 4'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-07T17:19:54', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'ead796e6-6a6b-4d1b-ae26-03a394adbd10' User entered 'Yes (Y)'	System	07 Aug 2020 21:20:15
	System	07 Aug 2020 21:20:15

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-07T17:19:59', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'ead796e6-6a6b-4d1b-ae26-03a394adbd10' User entered '98.1'	System	07 Aug 2020 21:20:15
	System	07 Aug 2020 21:20:15

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-07T17:20:03', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'ead796e6-6a6b-4d1b-ae26-03a394adbd10' User entered 'No (N)'	System	07 Aug 2020 21:20:15
	System	07 Aug 2020 21:20:15

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-07T17:20:10', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'ead796e6-6a6b-4d1b-ae26-03a394adbd10' User entered '07 Aug 2020 17:20'	System	07 Aug 2020 21:20:15
	System	07 Aug 2020 21:20:15

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 5'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-08T18:45:17', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'eed32908-edf3-40e2-85d9-363ddbe4cb70' User entered 'Yes (Y)'	System	08 Aug 2020 22:45:33
	System	08 Aug 2020 22:45:33

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-08T18:45:23', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'eed32908-edf3-40e2-85d9-363ddbe4cb70' User entered '98.2'	System	08 Aug 2020 22:45:33
	System	08 Aug 2020 22:45:33

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-08T18:45:26', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'eed32908-edf3-40e2-85d9-363ddbe4cb70'	System	08 Aug 2020 22:45:33
User entered 'No (N)'	System	08 Aug 2020 22:45:33

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-08T18:45:30', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'eed32908-edf3-40e2-85d9-363ddbe4cb70' User entered '08 Aug 2020 18:45'	System	08 Aug 2020 22:45:33
	System	08 Aug 2020 22:45:33

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 6'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-09T12:08:50', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '3d0d520d-e4ca-437e-a5de-1235fcb2f3b1' User entered 'Yes (Y)'	System	09 Aug 2020 16:09:05
	System	09 Aug 2020 16:09:05

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-09T12:08:56', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '3d0d520d-e4ca-437e-a5de-1235fcb2f3b1' User entered '98.0'	System	09 Aug 2020 16:09:05
	System	09 Aug 2020 16:09:05

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-09T12:08:59', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '3d0d520d-e4ca-437e-a5de-1235fcb2f3b1'	System	09 Aug 2020 16:09:05
User entered 'No (N)'	System	09 Aug 2020 16:09:05

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-09T12:09:03', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '3d0d520d-e4ca-437e-a5de-1235fcb2f3b1' User entered '09 Aug 2020 12:09'	System	09 Aug 2020 16:09:05
	System	09 Aug 2020 16:09:05

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 7'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-10T15:39:57', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'ff5bc79a-20a6-4721-bcef-269748dde803' User entered 'Yes (Y)'	System	10 Aug 2020 19:40:09
	System	10 Aug 2020 19:40:09

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-10T15:40:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'ff5bc79a-20a6-4721-bcef-269748dde803' User entered '97.3'	System	10 Aug 2020 19:40:09
	System	10 Aug 2020 19:40:09

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-10T15:40:03', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'ff5bc79a-20a6-4721-bcef-269748dde803'	System	10 Aug 2020 19:40:09
User entered 'No (N)'	System	10 Aug 2020 19:40:09

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-10T15:40:07', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'ff5bc79a-20a6-4721-bcef-269748dde803'	System	10 Aug 2020 19:40:09
User entered '10 Aug 2020 15:40'	System	10 Aug 2020 19:40:09

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-04T12:03:39', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4156128e-a847-447c-af30-3b2ce377daa3' User entered 'None (1)'	System	04 Aug 2020 16:04:20
	System	04 Aug 2020 16:04:20

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-04T12:03:48', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4156128e-a847-447c-af30-3b2ce377daa3'	System	04 Aug 2020 16:04:20
User entered 'No (N)'	System	04 Aug 2020 16:04:20

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-04T12:03:52', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4156128e-a847-447c-af30-3b2ce377daa3' User entered 'No (N)'	System	04 Aug 2020 16:04:20
	System	04 Aug 2020 16:04:20

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-04T12:04:11', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4156128e-a847-447c-af30-3b2ce377daa3'	System	04 Aug 2020 16:04:20
User entered 'None (1)'	System	04 Aug 2020 16:04:20

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-04T12:04:15', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4156128e-a847-447c-af30-3b2ce377daa3' User entered '04 Aug 2020 12:04'	System	04 Aug 2020 16:04:20
	System	04 Aug 2020 16:04:20

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '04 Aug 2020 11:44'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '04 Aug 2020 14:14'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-05T09:32:34', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '7617490e-92d2-47bf-a3c4-e8ee4c3716b0'	System	05 Aug 2020 13:36:37
User entered 'Does not interfere with activity (2)'	System	05 Aug 2020 13:36:37

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-05T09:31:10', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '7617490e-92d2-47bf-a3c4-e8ee4c3716b0' User entered 'No (N)'	System	05 Aug 2020 13:36:37
	System	05 Aug 2020 13:36:37

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-05T09:31:08', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '7617490e-92d2-47bf-a3c4-e8ee4c3716b0' User entered 'Yes (Y)'	System	05 Aug 2020 13:36:37
	System	05 Aug 2020 13:36:37

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-05T09:35:34', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '7617490e-92d2-47bf-a3c4-e8ee4c3716b0' User entered '2'	System	05 Aug 2020 13:36:37
	System	05 Aug 2020 13:36:37

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-05T09:36:10', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '7617490e-92d2-47bf-a3c4-e8ee4c3716b0' User entered 'None (1)'	System	05 Aug 2020 13:36:37
	System	05 Aug 2020 13:36:37

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-05T09:36:22', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '7617490e-92d2-47bf-a3c4-e8ee4c3716b0'	System	05 Aug 2020 13:36:37
User entered '05 Aug 2020 09:36'	System	05 Aug 2020 13:36:37

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '04 Aug 2020 15:09'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 2'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T09:22:57', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '8fb94ad2-9dcf-4b0e-99fd-21d103e7548c'	System	06 Aug 2020 13:23:21
User entered 'Does not interfere with activity (2)'	System	06 Aug 2020 13:23:21

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T09:23:01', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '8fb94ad2-9dcf-4b0e-99fd-21d103e7548c' User entered 'No (N)'	System	06 Aug 2020 13:23:21
	System	06 Aug 2020 13:23:21

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T09:23:03', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '8fb94ad2-9dcf-4b0e-99fd-21d103e7548c'	System	06 Aug 2020 13:23:21
User entered 'Yes (Y)'	System	06 Aug 2020 13:23:21

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T09:23:11', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '8fb94ad2-9dcf-4b0e-99fd-21d103e7548c' User entered '2'	System	06 Aug 2020 13:23:21
	System	06 Aug 2020 13:23:21

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T09:23:15', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '8fb94ad2-9dcf-4b0e-99fd-21d103e7548c' User entered 'None (1)'	System	06 Aug 2020 13:23:21
	System	06 Aug 2020 13:23:21

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T09:23:20', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '8fb94ad2-9dcf-4b0e-99fd-21d103e7548c' User entered '06 Aug 2020 09:23'	System	06 Aug 2020 13:23:21
	System	06 Aug 2020 13:23:21

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 3'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T17:00:43', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'd7c4cc0b-8a11-4b1f-a617-122012a49744'	System	06 Aug 2020 21:01:06
User entered 'Does not interfere with activity (2)'	System	06 Aug 2020 21:01:06

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T17:00:46', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'd7c4cc0b-8a11-4b1f-a617-122012a49744' User entered 'No (N)'	System	06 Aug 2020 21:01:06
	System	06 Aug 2020 21:01:06

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T17:00:48', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'd7c4cc0b-8a11-4b1f-a617-122012a49744' User entered 'No (N)'	System	06 Aug 2020 21:01:06
	System	06 Aug 2020 21:01:06

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T17:00:57', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'd7c4cc0b-8a11-4b1f-a617-122012a49744' User entered 'None (1)'	System	06 Aug 2020 21:01:06
	System	06 Aug 2020 21:01:06

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T17:01:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'd7c4cc0b-8a11-4b1f-a617-122012a49744' User entered '06 Aug 2020 17:01'	System	06 Aug 2020 21:01:06
	System	06 Aug 2020 21:01:06

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 4'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-07T17:20:14', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'fb0a82e4-2a88-4da3-868b-695ea451056a' User entered 'None (1)'	System	07 Aug 2020 21:20:27
	System	07 Aug 2020 21:20:27

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-07T17:20:17', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'fb0a82e4-2a88-4da3-868b-695ea451056a' User entered 'No (N)'	System	07 Aug 2020 21:20:27
	System	07 Aug 2020 21:20:27

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-07T17:20:19', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'fb0a82e4-2a88-4da3-868b-695ea451056a' User entered 'No (N)'	System	07 Aug 2020 21:20:27
	System	07 Aug 2020 21:20:27

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-07T17:20:23', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'fb0a82e4-2a88-4da3-868b-695ea451056a' User entered 'None (1)'	System	07 Aug 2020 21:20:27
	System	07 Aug 2020 21:20:27

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-07T17:20:25', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'fb0a82e4-2a88-4da3-868b-695ea451056a' User entered '07 Aug 2020 17:20'	System	07 Aug 2020 21:20:27
	System	07 Aug 2020 21:20:27

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 5'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-08T18:45:34', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '1a781b53-bf9c-441a-a3ac-a373ac82316e' User entered 'None (1)'	System	08 Aug 2020 22:45:50
	System	08 Aug 2020 22:45:50

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-08T18:45:37', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '1a781b53-bf9c-441a-a3ac-a373ac82316e' User entered 'No (N)'	System	08 Aug 2020 22:45:50
	System	08 Aug 2020 22:45:50

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-08T18:45:39', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '1a781b53-bf9c-441a-a3ac-a373ac82316e' User entered 'No (N)'	System	08 Aug 2020 22:45:50
	System	08 Aug 2020 22:45:50

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-08T18:45:42', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '1a781b53-bf9c-441a-a3ac-a373ac82316e' User entered 'None (1)'	System	08 Aug 2020 22:45:50
	System	08 Aug 2020 22:45:50

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-08T18:45:45', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '1a781b53-bf9c-441a-a3ac-a373ac82316e' User entered '08 Aug 2020 18:45'	System	08 Aug 2020 22:45:50
	System	08 Aug 2020 22:45:50

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 6'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-09T12:09:08', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4fe986a2-b750-4039-9874-4d07e4d9a0a0' User entered 'None (1)'	System	09 Aug 2020 16:09:21
	System	09 Aug 2020 16:09:21

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-09T12:09:10', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4fe986a2-b750-4039-9874-4d07e4d9a0a0' User entered 'No (N)'	System	09 Aug 2020 16:09:21
	System	09 Aug 2020 16:09:21

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-09T12:09:13', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4fe986a2-b750-4039-9874-4d07e4d9a0a0' User entered 'No (N)'	System	09 Aug 2020 16:09:21
	System	09 Aug 2020 16:09:21

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-09T12:09:16', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4fe986a2-b750-4039-9874-4d07e4d9a0a0' User entered 'None (1)'	System	09 Aug 2020 16:09:21
	System	09 Aug 2020 16:09:21

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-09T12:09:18', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4fe986a2-b750-4039-9874-4d07e4d9a0a0' User entered '09 Aug 2020 12:09'	System	09 Aug 2020 16:09:21
	System	09 Aug 2020 16:09:21

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 7'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-10T15:40:11', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'df275b13-fdfa-4fd4-b3c7-8ce4a70cb322'	System	10 Aug 2020 19:40:22
User entered 'None (1)'	System	10 Aug 2020 19:40:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-10T15:40:13', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'df275b13-fdfa-4fd4-b3c7-8ce4a70cb322'	System	10 Aug 2020 19:40:22
User entered 'No (N)'	System	10 Aug 2020 19:40:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-10T15:40:15', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'df275b13-fdfa-4fd4-b3c7-8ce4a70cb322'	System	10 Aug 2020 19:40:22
User entered 'No (N)'	System	10 Aug 2020 19:40:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-10T15:40:18', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'df275b13-fdfa-4fd4-b3c7-8ce4a70cb322'	System	10 Aug 2020 19:40:22
User entered 'None (1)'	System	10 Aug 2020 19:40:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-10T15:40:20', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'df275b13-fdfa-4fd4-b3c7-8ce4a70cb322'	System	10 Aug 2020 19:40:22
User entered '10 Aug 2020 15:40'	System	10 Aug 2020 19:40:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-04T12:04:44', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '332f0f4f-591c-44f7-9b17-96159e6142ba' User entered 'None (0)'	System	04 Aug 2020 16:05:52
	System	04 Aug 2020 16:05:52

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-04T12:05:22', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '332f0f4f-591c-44f7-9b17-96159e6142ba' User entered 'None (0)'	System	04 Aug 2020 16:05:52
	System	04 Aug 2020 16:05:52

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-04T12:05:26', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '332f0f4f-591c-44f7-9b17-96159e6142ba' User entered 'None (0)'	System	04 Aug 2020 16:05:52
	System	04 Aug 2020 16:05:52

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-04T12:05:29', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '332f0f4f-591c-44f7-9b17-96159e6142ba' User entered 'None (0)'	System	04 Aug 2020 16:05:52
	System	04 Aug 2020 16:05:52

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-04T12:05:32', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '332f0f4f-591c-44f7-9b17-96159e6142ba' User entered 'None (0)'	System	04 Aug 2020 16:05:52
	System	04 Aug 2020 16:05:52

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-04T12:05:35', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '332f0f4f-591c-44f7-9b17-96159e6142ba' User entered 'None (0)'	System	04 Aug 2020 16:05:52
	System	04 Aug 2020 16:05:52

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-04T12:05:44', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '332f0f4f-591c-44f7-9b17-96159e6142ba' User entered 'No (N)'	System	04 Aug 2020 16:05:52
	System	04 Aug 2020 16:05:52

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-04T12:05:46', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '332f0f4f-591c-44f7-9b17-96159e6142ba' User entered '04 Aug 2020 12:05'	System	04 Aug 2020 16:05:52
	System	04 Aug 2020 16:05:52

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '04 Aug 2020 11:44'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '04 Aug 2020 14:14'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-05T09:36:27', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'a8364759-3a6e-4ee6-aeaf-fea56e1725c6' User entered 'None (0)'	System	05 Aug 2020 13:37:22
	System	05 Aug 2020 13:37:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-05T09:36:42', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'a8364759-3a6e-4ee6-aeaf-fea56e1725c6'	System	05 Aug 2020 13:37:22
User entered 'No interference with activity (1)'	System	05 Aug 2020 13:37:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-05T09:36:49', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'a8364759-3a6e-4ee6-aeaf-fea56e1725c6' User entered 'None (0)'	System	05 Aug 2020 13:37:22
	System	05 Aug 2020 13:37:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-05T09:36:54', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'a8364759-3a6e-4ee6-aeaf-fea56e1725c6' User entered 'None (0)'	System	05 Aug 2020 13:37:22
	System	05 Aug 2020 13:37:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-05T09:36:56', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'a8364759-3a6e-4ee6-aeaf-fea56e1725c6' User entered 'None (0)'	System	05 Aug 2020 13:37:22
	System	05 Aug 2020 13:37:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-05T09:37:02', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'a8364759-3a6e-4ee6-aeaf-fea56e1725c6' User entered 'None (0)'	System	05 Aug 2020 13:37:22
	System	05 Aug 2020 13:37:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-05T09:37:16', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'a8364759-3a6e-4ee6-aeaf-fea56e1725c6'	System	05 Aug 2020 13:37:22
User entered 'No (N)'	System	05 Aug 2020 13:37:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-05T09:37:19', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'a8364759-3a6e-4ee6-aeaf-fea56e1725c6' User entered '05 Aug 2020 09:37'	System	05 Aug 2020 13:37:22
	System	05 Aug 2020 13:37:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '04 Aug 2020 15:09'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 2'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T09:23:27', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '89281e8c-6f2b-4695-a714-4f252ffa7a3f' User entered 'None (0)'	System	06 Aug 2020 13:23:48
	System	06 Aug 2020 13:23:48

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T09:23:30', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '89281e8c-6f2b-4695-a714-4f252ffa7a3f'	System	06 Aug 2020 13:23:48
User entered 'No interference with activity (1)'	System	06 Aug 2020 13:23:48

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T09:23:33', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '89281e8c-6f2b-4695-a714-4f252ffa7a3f' User entered 'None (0)'	System	06 Aug 2020 13:23:48
	System	06 Aug 2020 13:23:48

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T09:23:36', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '89281e8c-6f2b-4695-a714-4f252ffa7a3f' User entered 'None (0)'	System	06 Aug 2020 13:23:48
	System	06 Aug 2020 13:23:48

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T09:23:38', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '89281e8c-6f2b-4695-a714-4f252ffa7a3f' User entered 'None (0)'	System	06 Aug 2020 13:23:48
	System	06 Aug 2020 13:23:48

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T09:23:40', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '89281e8c-6f2b-4695-a714-4f252ffa7a3f' User entered 'None (0)'	System	06 Aug 2020 13:23:48
	System	06 Aug 2020 13:23:48

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T09:23:44', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '89281e8c-6f2b-4695-a714-4f252ffa7a3f' User entered 'No (N)'	System	06 Aug 2020 13:23:48
	System	06 Aug 2020 13:23:48

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T09:23:46', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '89281e8c-6f2b-4695-a714-4f252ffa7a3f' User entered '06 Aug 2020 09:23'	System	06 Aug 2020 13:23:48
	System	06 Aug 2020 13:23:48

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 3'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T17:01:05', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '9ae11e76-7f70-4daa-8ada-516d4c74c146' User entered 'None (0)'	System	06 Aug 2020 21:01:30
	System	06 Aug 2020 21:01:30

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T17:01:08', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '9ae11e76-7f70-4daa-8ada-516d4c74c146' User entered 'None (0)'	System	06 Aug 2020 21:01:30
	System	06 Aug 2020 21:01:30

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T17:01:10', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '9ae11e76-7f70-4daa-8ada-516d4c74c146' User entered 'None (0)'	System	06 Aug 2020 21:01:30
	System	06 Aug 2020 21:01:30

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T17:01:11', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '9ae11e76-7f70-4daa-8ada-516d4c74c146' User entered 'None (0)'	System	06 Aug 2020 21:01:30
	System	06 Aug 2020 21:01:30

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T17:01:13', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '9ae11e76-7f70-4daa-8ada-516d4c74c146' User entered 'None (0)'	System	06 Aug 2020 21:01:30
	System	06 Aug 2020 21:01:30

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T17:01:15', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '9ae11e76-7f70-4daa-8ada-516d4c74c146' User entered 'None (0)'	System	06 Aug 2020 21:01:30
	System	06 Aug 2020 21:01:30

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T17:01:23', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '9ae11e76-7f70-4daa-8ada-516d4c74c146' User entered 'No (N)'	System	06 Aug 2020 21:01:30
	System	06 Aug 2020 21:01:30

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-06T17:01:25', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '9ae11e76-7f70-4daa-8ada-516d4c74c146' User entered '06 Aug 2020 17:01'	System	06 Aug 2020 21:01:30
	System	06 Aug 2020 21:01:30

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 4'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-07T17:20:30', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '7c642bd8-3a90-4119-9be9-f5b15e7eac55'	System	07 Aug 2020 21:20:50
User entered 'None (0)'	System	07 Aug 2020 21:20:50

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-07T17:20:32', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '7c642bd8-3a90-4119-9be9-f5b15e7eac55'	System	07 Aug 2020 21:20:50
User entered 'None (0)'	System	07 Aug 2020 21:20:50

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-07T17:20:35', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '7c642bd8-3a90-4119-9be9-f5b15e7eac55'	System	07 Aug 2020 21:20:50
User entered 'None (0)'	System	07 Aug 2020 21:20:50

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-07T17:20:37', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '7c642bd8-3a90-4119-9be9-f5b15e7eac55'	System	07 Aug 2020 21:20:50
User entered 'None (0)'	System	07 Aug 2020 21:20:50

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-07T17:20:40', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '7c642bd8-3a90-4119-9be9-f5b15e7eac55' User entered 'None (0)'	System	07 Aug 2020 21:20:50
	System	07 Aug 2020 21:20:50

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-07T17:20:42', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '7c642bd8-3a90-4119-9be9-f5b15e7eac55'	System	07 Aug 2020 21:20:50
User entered 'None (0)'	System	07 Aug 2020 21:20:50

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-07T17:20:45', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '7c642bd8-3a90-4119-9be9-f5b15e7eac55'	System	07 Aug 2020 21:20:50
User entered 'No (N)'	System	07 Aug 2020 21:20:50

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-07T17:20:47', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '7c642bd8-3a90-4119-9be9-f5b15e7eac55'	System	07 Aug 2020 21:20:50
User entered '07 Aug 2020 17:20'	System	07 Aug 2020 21:20:50

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 5'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-08T18:45:48', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '7453990c-61d8-4317-8adc-a3324e6a62f1' User entered 'None (0)'	System	08 Aug 2020 22:46:06
	System	08 Aug 2020 22:46:06

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-08T18:45:50', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '7453990c-61d8-4317-8adc-a3324e6a62f1' User entered 'None (0)'	System	08 Aug 2020 22:46:06
	System	08 Aug 2020 22:46:06

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-08T18:45:52', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '7453990c-61d8-4317-8adc-a3324e6a62f1' User entered 'None (0)'	System	08 Aug 2020 22:46:06
	System	08 Aug 2020 22:46:06

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-08T18:45:54', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '7453990c-61d8-4317-8adc-a3324e6a62f1' User entered 'None (0)'	System	08 Aug 2020 22:46:06
	System	08 Aug 2020 22:46:06

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-08T18:45:56', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '7453990c-61d8-4317-8adc-a3324e6a62f1' User entered 'None (0)'	System	08 Aug 2020 22:46:06
	System	08 Aug 2020 22:46:06

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-08T18:45:57', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '7453990c-61d8-4317-8adc-a3324e6a62f1' User entered 'None (0)'	System	08 Aug 2020 22:46:06
	System	08 Aug 2020 22:46:06

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-08T18:46:01', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '7453990c-61d8-4317-8adc-a3324e6a62f1' User entered 'No (N)'	System	08 Aug 2020 22:46:06
	System	08 Aug 2020 22:46:06

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-08T18:46:04', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '7453990c-61d8-4317-8adc-a3324e6a62f1' User entered '08 Aug 2020 18:46'	System	08 Aug 2020 22:46:06
	System	08 Aug 2020 22:46:06

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 6'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-09T12:09:22', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'b8061043-213a-4b27-9283-5f2285d9775e' User entered 'None (0)'	System	09 Aug 2020 16:09:35
	System	09 Aug 2020 16:09:35

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-09T12:09:23', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'b8061043-213a-4b27-9283-5f2285d9775e' User entered 'None (0)'	System	09 Aug 2020 16:09:35
	System	09 Aug 2020 16:09:35

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-09T12:09:24', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'b8061043-213a-4b27-9283-5f2285d9775e' User entered 'None (0)'	System	09 Aug 2020 16:09:35
	System	09 Aug 2020 16:09:35

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-09T12:09:26', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'b8061043-213a-4b27-9283-5f2285d9775e' User entered 'None (0)'	System	09 Aug 2020 16:09:35
	System	09 Aug 2020 16:09:35

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-09T12:09:27', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'b8061043-213a-4b27-9283-5f2285d9775e' User entered 'None (0)'	System	09 Aug 2020 16:09:35
	System	09 Aug 2020 16:09:35

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-09T12:09:28', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'b8061043-213a-4b27-9283-5f2285d9775e' User entered 'None (0)'	System	09 Aug 2020 16:09:35
	System	09 Aug 2020 16:09:35

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-09T12:09:30', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'b8061043-213a-4b27-9283-5f2285d9775e' User entered 'No (N)'	System	09 Aug 2020 16:09:35
	System	09 Aug 2020 16:09:35

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-09T12:09:32', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'b8061043-213a-4b27-9283-5f2285d9775e' User entered '09 Aug 2020 12:09'	System	09 Aug 2020 16:09:35
	System	09 Aug 2020 16:09:35

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 7'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-10T15:40:24', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '84b7bdf8-5c30-4e06-953b-56574a0119da' User entered 'None (0)'	System	10 Aug 2020 19:40:38
	System	10 Aug 2020 19:40:38

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-10T15:40:26', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '84b7bdf8-5c30-4e06-953b-56574a0119da' User entered 'None (0)'	System	10 Aug 2020 19:40:38
	System	10 Aug 2020 19:40:38

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-10T15:40:27', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '84b7bdf8-5c30-4e06-953b-56574a0119da' User entered 'None (0)'	System	10 Aug 2020 19:40:38
	System	10 Aug 2020 19:40:38

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-10T15:40:29', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '84b7bdf8-5c30-4e06-953b-56574a0119da' User entered 'None (0)'	System	10 Aug 2020 19:40:38
	System	10 Aug 2020 19:40:38

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-10T15:40:31', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '84b7bdf8-5c30-4e06-953b-56574a0119da' User entered 'None (0)'	System	10 Aug 2020 19:40:38
	System	10 Aug 2020 19:40:38

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-10T15:40:33', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '84b7bdf8-5c30-4e06-953b-56574a0119da' User entered 'None (0)'	System	10 Aug 2020 19:40:38
	System	10 Aug 2020 19:40:38

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-10T15:40:35', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '84b7bdf8-5c30-4e06-953b-56574a0119da' User entered 'No (N)'	System	10 Aug 2020 19:40:38
	System	10 Aug 2020 19:40:38

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-08-10T15:40:37', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '84b7bdf8-5c30-4e06-953b-56574a0119da' User entered '10 Aug 2020 15:40'	System	10 Aug 2020 19:40:38
	System	10 Aug 2020 19:40:38

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 15:35:22

US3822003

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 15:35:22

US3822003

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	26 Aug 2020 01:14:55

US3822003

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '12 Aug 2020'	Kelly Woodell (b) (4)	26 Aug 2020 01:14:55

US3822003

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4)	26 Aug 2020 01:14:55

US3822003

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered empty.	Kelly Woodell (b) (4)	26 Aug 2020 01:14:55

US3822003

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	26 Aug 2020 01:15:00

US3822003

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'I'	System	26 Aug 2020 01:15:00

US3822003

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:25:06

US3822003

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:25:06

US3822003

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:25:06

US3822003

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'not done'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:25:06

US3822003

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:25:12

US3822003

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'I'	System	01 Sep 2020 15:25:12

US3822003

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:25:32

US3822003

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:25:32

US3822003

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:25:32

US3822003

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:25:32

US3822003

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:25:42

US3822003

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'I'	System	01 Sep 2020 15:25:42

US3822003

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Sep 2020 15:08:14

US3822003

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '1 Sep 2020'	Krishna Shah (b) (4)	28 Sep 2020 15:08:14

US3822003

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:59

[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 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Clinic (Clinic)'	Krishna Shah (b) (4)	28 Sep 2020 15:08:14

US3822003

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'VISIT2'	System	28 Sep 2020 15:08:14

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User accepted default value 'Pre-Dose (PREDOSE)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:09:08

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Sep 2020 15:09:08

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '1 Sep 2020'	Krishna Shah (b) (4)	28 Sep 2020 15:09:08

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '09:51'	Krishna Shah (b) (4)	28 Sep 2020 15:09:08

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered '1 Sep 2020 09:51'	System	28 Sep 2020 15:09:08

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '98.5' F	Krishna Shah (b) (4)	28 Sep 2020 15:09:08

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Oral (Oral)'	Krishna Shah (b) (4)	28 Sep 2020 15:09:08

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 15:09:08

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '66'	Krishna Shah (b) (4)	28 Sep 2020 15:09:08

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'bpm'	System	28 Sep 2020 15:09:08

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '12'	Krishna Shah (b) (4)	28 Sep 2020 15:09:08

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'breaths/min'	System	28 Sep 2020 15:09:08

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '128'	Krishna Shah (b) (4)	28 Sep 2020 15:09:08

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'mmHg'	System	28 Sep 2020 15:09:08

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '84'	Krishna Shah (b) (4)	28 Sep 2020 15:09:08

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'mmHg'	System	28 Sep 2020 15:09:08

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User accepted default value 'Post-Dose (POSTDOSE)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:09:41

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Sep 2020 15:09:41

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '1 Sep 2020'	Krishna Shah (b) (4)	28 Sep 2020 15:09:41

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '11:30'	Krishna Shah (b) (4)	28 Sep 2020 15:09:41

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered '1 Sep 2020 11:30'	System	28 Sep 2020 15:09:41

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '98.4' F	Krishna Shah (b) (4)	28 Sep 2020 15:09:41

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Oral (Oral)'	Krishna Shah (b) (4)	28 Sep 2020 15:09:41

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 15:09:41

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '60'	Krishna Shah (b) (4)	28 Sep 2020 15:09:41

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'bpm'	System	28 Sep 2020 15:09:41

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '12'	Krishna Shah (b) (4)	28 Sep 2020 15:09:41

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'breaths/min'	System	28 Sep 2020 15:09:41

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '132'	Krishna Shah (b) (4)	28 Sep 2020 15:09:41

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'mmHg'	System	28 Sep 2020 15:09:41

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '86'	Krishna Shah (b) (4)	28 Sep 2020 15:09:41

US3822003

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'mmHg'	System	28 Sep 2020 15:09:41

US3822003

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'No (N)'	Krishna Shah (b) (4)	28 Sep 2020 15:09:58

US3822003

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 15:09:58

US3822003

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User closed query 'Per CDM: Please complete all other applicable forms for this visit 2. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 12:40:49
Query 'Per CDM: Please complete all other applicable forms for this visit 2. ' answered with 'updated ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:21:41
User opened query 'Per CDM: Please complete all other applicable forms for this visit 2. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 11:25:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 15:26:14

US3822003

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:26:14

US3822003

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:59

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 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:26:14

US3822003

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 15:26:14

US3822003

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '01 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:26:14

US3822003

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '10:56'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:26:14

US3822003

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered '01 Sep 2020 10:56'	System	01 Sep 2020 15:26:14

US3822003

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:59

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:26:14

US3822003

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'ONCE'	System	01 Sep 2020 15:26:14

US3822003

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 15:26:14

US3822003

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Sep 2020 15:10:13

US3822003

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '1 Sep 2020'	Krishna Shah (b) (4)	28 Sep 2020 15:10:13

US3822003

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '10:01'	Krishna Shah (b) (4)	28 Sep 2020 15:10:13

US3822003

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered '1 Sep 2020 10:01'	System	28 Sep 2020 15:10:13

US3822003

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:00:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '1 Sep 2020'	Krishna Shah (b) (4)	28 Sep 2020 15:10:28

US3822003

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:10:28

US3822003

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Sep 2020 15:10:28

US3822003

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '10:30'	Krishna Shah (b) (4)	28 Sep 2020 15:10:28

US3822003

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered '1 Sep 2020 10:30'	System	28 Sep 2020 15:10:28

US3822003

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:10:28

US3822003

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'No (N)'	Krishna Shah (b) (4)	28 Sep 2020 15:10:28

US3822003

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 15:10:28

US3822003

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered empty.	System	28 Sep 2020 15:10:28

US3822003

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Sep 2020 15:10:34

US3822003

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'I'	System	28 Sep 2020 15:10:34

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	01 Sep 2020 15:26:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T11:28:42', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '2a38089b-1b77-4dba-8123-03889a2a3115' User entered 'Yes (Y)'	System	01 Sep 2020 15:29:07
	System	01 Sep 2020 15:29:07

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T11:28:48', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '2a38089b-1b77-4dba-8123-03889a2a3115' User entered '98.4'	System	01 Sep 2020 15:29:07
	System	01 Sep 2020 15:29:07

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T11:28:51', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '2a38089b-1b77-4dba-8123-03889a2a3115'	System	01 Sep 2020 15:29:07
User entered 'No (N)'	System	01 Sep 2020 15:29:07

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T11:29:03', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '2a38089b-1b77-4dba-8123-03889a2a3115' User entered '01 Sep 2020 11:29'	System	01 Sep 2020 15:29:07
	System	01 Sep 2020 15:29:07

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '01 Sep 2020 11:16'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '01 Sep 2020 13:46'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	01 Sep 2020 15:26:14
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T19:05:15', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '14eaec6c-bf5f-49ab-878a-b649670ff8e4' User entered 'Yes (Y)'	System	01 Sep 2020 23:05:31
	System	01 Sep 2020 23:05:31

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T19:05:21', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '14eac6c-bf5f-49ab-878a-b649670ff8e4' User entered '97.5'	System	01 Sep 2020 23:05:31
	System	01 Sep 2020 23:05:31

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T19:05:25', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '14eaec6c-bf5f-49ab-878a-b649670ff8e4'	System	01 Sep 2020 23:05:31
User entered 'No (N)'	System	01 Sep 2020 23:05:31

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T19:05:30', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '14eaec6c-bf5f-49ab-878a-b649670ff8e4'	System	01 Sep 2020 23:05:31
User entered '01 Sep 2020 19:05'	System	01 Sep 2020 23:05:31

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '01 Sep 2020 14:41'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	01 Sep 2020 15:26:14
User entered 'Day 2'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-02T16:43:48', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '86098176-4d10-49a7-a247-95f0284288dd' User entered 'Yes (Y)'	System	02 Sep 2020 20:44:28
	System	02 Sep 2020 20:44:28

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-02T16:43:53', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '86098176-4d10-49a7-a247-95f0284288dd' User entered '99.5'	System	02 Sep 2020 20:44:28
	System	02 Sep 2020 20:44:28

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-02T16:43:56', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '86098176-4d10-49a7-a247-95f0284288dd'	System	02 Sep 2020 20:44:28
User entered 'Yes (Y)'	System	02 Sep 2020 20:44:28

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'medication added' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 07:50:43
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Kelly Woodell (b) (4)	16 Sep 2020 22:19:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-02T16:44:18', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '86098176-4d10-49a7-a247-95f0284288dd'	System	02 Sep 2020 20:44:28
User entered '1'	System	02 Sep 2020 20:44:28

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:59

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-02T16:44:18', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '86098176-4d10-49a7-a247-95f0284288dd' User entered '0'	System	02 Sep 2020 20:44:28
	System	02 Sep 2020 20:44:28

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-02T16:44:25', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '86098176-4d10-49a7-a247-95f0284288dd' User entered '02 Sep 2020 16:44'	System	02 Sep 2020 20:44:28
	System	02 Sep 2020 20:44:28

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	01 Sep 2020 15:26:14
User entered 'Day 3'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-03T21:54:05', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '368fd52c-2496-4ffb-8b21-5b541884cd89' User entered 'Yes (Y)'	System	04 Sep 2020 01:54:27
	System	04 Sep 2020 01:54:27

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-03T21:54:17', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '368fd52c-2496-4ffb-8b21-5b541884cd89' User entered '98.4'	System	04 Sep 2020 01:54:27
	System	04 Sep 2020 01:54:27

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-03T21:54:21', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '368fd52c-2496-4ffb-8b21-5b541884cd89'	System	04 Sep 2020 01:54:27
User entered 'No (N)'	System	04 Sep 2020 01:54:27

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-03T21:54:25', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '368fd52c-2496-4ffb-8b21-5b541884cd89' User entered '03 Sep 2020 21:54'	System	04 Sep 2020 01:54:27
	System	04 Sep 2020 01:54:27

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	01 Sep 2020 15:26:14
User entered 'Day 4'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-04T17:33:09', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'e1929214-3a35-46c3-b9a5-b1b03c93426f' User entered 'Yes (Y)'	System	04 Sep 2020 21:33:22
	System	04 Sep 2020 21:33:22

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-04T17:33:14', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'e1929214-3a35-46c3-b9a5-b1b03c93426f' User entered '97.5'	System	04 Sep 2020 21:33:22
	System	04 Sep 2020 21:33:22

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-04T17:33:16', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'e1929214-3a35-46c3-b9a5-b1b03c93426f' User entered 'No (N)'	System	04 Sep 2020 21:33:22
	System	04 Sep 2020 21:33:22

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-04T17:33:20', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'e1929214-3a35-46c3-b9a5-b1b03c93426f' User entered '04 Sep 2020 17:33'	System	04 Sep 2020 21:33:22
	System	04 Sep 2020 21:33:22

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	01 Sep 2020 15:26:14
User entered 'Day 5'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-05T19:45:22', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'f01fb7be-2916-4e2c-b634-5c4642b2da76' User entered 'Yes (Y)'	System	05 Sep 2020 23:45:42
	System	05 Sep 2020 23:45:42

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-05T19:45:30', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'f01fb7be-2916-4e2c-b634-5c4642b2da76' User entered '97.5'	System	05 Sep 2020 23:45:42
	System	05 Sep 2020 23:45:42

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-05T19:45:34', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'f01fb7be-2916-4e2c-b634-5c4642b2da76'	System	05 Sep 2020 23:45:42
User entered 'No (N)'	System	05 Sep 2020 23:45:42

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-05T19:45:41', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'f01fb7be-2916-4e2c-b634-5c4642b2da76' User entered '05 Sep 2020 19:45'	System	05 Sep 2020 23:45:42
	System	05 Sep 2020 23:45:42

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	01 Sep 2020 15:26:14
User entered 'Day 6'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-06T15:00:19', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '13fcedb5-0702-4d46-be57-45ab3b9798b8' User entered 'Yes (Y)'	System	06 Sep 2020 19:00:52
	System	06 Sep 2020 19:00:52

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-06T15:00:39', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '13fcedb5-0702-4d46-be57-45ab3b9798b8' User entered '97.4'	System	06 Sep 2020 19:00:52
	System	06 Sep 2020 19:00:52

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-06T15:00:43', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '13fcedb5-0702-4d46-be57-45ab3b9798b8' User entered 'No (N)'	System	06 Sep 2020 19:00:52
	System	06 Sep 2020 19:00:52

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-06T15:00:48', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '13fcedb5-0702-4d46-be57-45ab3b9798b8' User entered '06 Sep 2020 15:00'	System	06 Sep 2020 19:00:52
	System	06 Sep 2020 19:00:52

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	01 Sep 2020 15:26:14
User entered 'Day 7'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-07T19:10:15', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '6e948272-0405-4f98-ae5a-da0148d0cd34' User entered 'Yes (Y)'	System	07 Sep 2020 23:10:32
	System	07 Sep 2020 23:10:32

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-07T19:10:20', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '6e948272-0405-4f98-ae5a-da0148d0cd34' User entered '98.0'	System	07 Sep 2020 23:10:32
	System	07 Sep 2020 23:10:32

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-07T19:10:25', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '6e948272-0405-4f98-ae5a-da0148d0cd34' User entered 'No (N)'	System	07 Sep 2020 23:10:32
	System	07 Sep 2020 23:10:32

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-07T19:10:29', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '6e948272-0405-4f98-ae5a-da0148d0cd34' User entered '07 Sep 2020 19:10'	System	07 Sep 2020 23:10:32
	System	07 Sep 2020 23:10:32

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	01 Sep 2020 15:26:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T11:29:55', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'e1ab5e7e-eee1-401a-95fb-a631b97a3ed9' User entered 'None (1)'	System	01 Sep 2020 15:30:22
	System	01 Sep 2020 15:30:22

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T11:30:07', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'e1ab5e7e-eee1-401a-95fb-a631b97a3ed9'	System	01 Sep 2020 15:30:22
User entered 'No (N)'	System	01 Sep 2020 15:30:22

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T11:30:14', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'e1ab5e7e-eee1-401a-95fb-a631b97a3ed9' User entered 'No (N)'	System	01 Sep 2020 15:30:22
	System	01 Sep 2020 15:30:22

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T11:30:16', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'e1ab5e7e-eee1-401a-95fb-a631b97a3ed9' User entered 'None (1)'	System	01 Sep 2020 15:30:22
	System	01 Sep 2020 15:30:22

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T11:30:19', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'e1ab5e7e-eee1-401a-95fb-a631b97a3ed9'	System	01 Sep 2020 15:30:22
User entered '01 Sep 2020 11:30'	System	01 Sep 2020 15:30:22

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '01 Sep 2020 11:16'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '01 Sep 2020 13:46'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	01 Sep 2020 15:26:14
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T19:05:36', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c97f4080-40c7-4dd3-8ee3-90c1a6a81d1e'	System	01 Sep 2020 23:06:12
User entered 'Does not interfere with activity (2)'	System	01 Sep 2020 23:06:12

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T19:05:40', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c97f4080-40c7-4dd3-8ee3-90c1a6a81d1e' User entered 'No (N)'	System	01 Sep 2020 23:06:12
	System	01 Sep 2020 23:06:12

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T19:05:43', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c97f4080-40c7-4dd3-8ee3-90c1a6a81d1e' User entered 'Yes (Y)'	System	01 Sep 2020 23:06:12
	System	01 Sep 2020 23:06:12

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T19:06:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c97f4080-40c7-4dd3-8ee3-90c1a6a81d1e' User entered '3'	System	01 Sep 2020 23:06:12
	System	01 Sep 2020 23:06:12

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T19:06:04', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c97f4080-40c7-4dd3-8ee3-90c1a6a81d1e' User entered 'None (1)'	System	01 Sep 2020 23:06:12
	System	01 Sep 2020 23:06:12

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T19:06:07', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c97f4080-40c7-4dd3-8ee3-90c1a6a81d1e' User entered '01 Sep 2020 19:06'	System	01 Sep 2020 23:06:12
	System	01 Sep 2020 23:06:12

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '01 Sep 2020 14:41'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	01 Sep 2020 15:26:14
User entered 'Day 2'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-02T16:44:34', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '8ad5ffab-6868-4aeb-9a74-400f973f120b' User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 20:45:15
	System	02 Sep 2020 20:45:15

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-02T16:44:48', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '8ad5ffab-6868-4aeb-9a74-400f973f120b' User entered 'No (N)'	System	02 Sep 2020 20:45:15
	System	02 Sep 2020 20:45:15

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-02T16:44:51', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '8ad5ffab-6868-4aeb-9a74-400f973f120b' User entered 'Yes (Y)'	System	02 Sep 2020 20:45:15
	System	02 Sep 2020 20:45:15

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-02T16:45:04', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '8ad5ffab-6868-4aeb-9a74-400f973f120b' User entered '3'	System	02 Sep 2020 20:45:15
	System	02 Sep 2020 20:45:15

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-02T16:45:09', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '8ad5ffab-6868-4aeb-9a74-400f973f120b' User entered 'None (1)'	System	02 Sep 2020 20:45:15
	System	02 Sep 2020 20:45:15

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-02T16:45:13', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '8ad5ffab-6868-4aeb-9a74-400f973f120b'	System	02 Sep 2020 20:45:15
User entered '02 Sep 2020 16:45'	System	02 Sep 2020 20:45:15

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	01 Sep 2020 15:26:14
User entered 'Day 3'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-03T21:54:41', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c15f08d3-6ed0-47a3-8cb5-2c3d40e0787b'	System	04 Sep 2020 01:55:03
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 01:55:03

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-03T21:54:44', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c15f08d3-6ed0-47a3-8cb5-2c3d40e0787b' User entered 'No (N)'	System	04 Sep 2020 01:55:03
	System	04 Sep 2020 01:55:03

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-03T21:54:48', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c15f08d3-6ed0-47a3-8cb5-2c3d40e0787b' User entered 'No (N)'	System	04 Sep 2020 01:55:03
	System	04 Sep 2020 01:55:03

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-03T21:54:51', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c15f08d3-6ed0-47a3-8cb5-2c3d40e0787b' User entered 'None (1)'	System	04 Sep 2020 01:55:03
	System	04 Sep 2020 01:55:03

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-03T21:54:58', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c15f08d3-6ed0-47a3-8cb5-2c3d40e0787b' User entered '03 Sep 2020 21:54'	System	04 Sep 2020 01:55:03
	System	04 Sep 2020 01:55:03

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	01 Sep 2020 15:26:14
User entered 'Day 4'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-04T17:33:27', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c911add6-2b31-4b41-9f51-e88c85256469' User entered 'None (1)'	System	04 Sep 2020 21:33:40
	System	04 Sep 2020 21:33:40

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-04T17:33:30', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c911add6-2b31-4b41-9f51-e88c85256469' User entered 'No (N)'	System	04 Sep 2020 21:33:40
	System	04 Sep 2020 21:33:40

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-04T17:33:32', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c911add6-2b31-4b41-9f51-e88c85256469' User entered 'No (N)'	System	04 Sep 2020 21:33:40
	System	04 Sep 2020 21:33:40

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-04T17:33:36', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c911add6-2b31-4b41-9f51-e88c85256469' User entered 'None (1)'	System	04 Sep 2020 21:33:40
	System	04 Sep 2020 21:33:40

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-04T17:33:38', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c911add6-2b31-4b41-9f51-e88c85256469' User entered '04 Sep 2020 17:33'	System	04 Sep 2020 21:33:40
	System	04 Sep 2020 21:33:40

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	01 Sep 2020 15:26:14
User entered 'Day 5'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-05T19:45:46', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '889f06ca-159f-4faa-bfd7-7394c425e808'	System	05 Sep 2020 23:46:01
User entered 'None (1)'	System	05 Sep 2020 23:46:01

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-05T19:45:49', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '889f06ca-159f-4faa-bfd7-7394c425e808'	System	05 Sep 2020 23:46:01
User entered 'No (N)'	System	05 Sep 2020 23:46:01

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-05T19:45:52', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '889f06ca-159f-4faa-bfd7-7394c425e808'	System	05 Sep 2020 23:46:01
User entered 'No (N)'	System	05 Sep 2020 23:46:01

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-05T19:45:55', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '889f06ca-159f-4faa-bfd7-7394c425e808'	System	05 Sep 2020 23:46:01
User entered 'None (1)'	System	05 Sep 2020 23:46:01

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-05T19:45:58', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '889f06ca-159f-4faa-bfd7-7394c425e808' User entered '05 Sep 2020 19:45'	System	05 Sep 2020 23:46:01
	System	05 Sep 2020 23:46:01

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	01 Sep 2020 15:26:14
User entered 'Day 6'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-06T15:00:53', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '41d5c19b-3d8e-4636-8dc6-fa4ac7126eef' User entered 'None (1)'	System	06 Sep 2020 19:01:08
	System	06 Sep 2020 19:01:08

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-06T15:00:56', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '41d5c19b-3d8e-4636-8dc6-fa4ac7126eef' User entered 'No (N)'	System	06 Sep 2020 19:01:08
	System	06 Sep 2020 19:01:08

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-06T15:00:58', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '41d5c19b-3d8e-4636-8dc6-fa4ac7126eef' User entered 'No (N)'	System	06 Sep 2020 19:01:08
	System	06 Sep 2020 19:01:08

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-06T15:01:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '41d5c19b-3d8e-4636-8dc6-fa4ac7126eef'	System	06 Sep 2020 19:01:08
User entered 'None (1)'	System	06 Sep 2020 19:01:08

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-06T15:01:03', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '41d5c19b-3d8e-4636-8dc6-fa4ac7126eef' User entered '06 Sep 2020 15:01'	System	06 Sep 2020 19:01:08
	System	06 Sep 2020 19:01:08

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	01 Sep 2020 15:26:14
User entered 'Day 7'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-07T19:10:32', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '67aab04b-de44-4087-a741-08f0a7589a32'	System	07 Sep 2020 23:10:45
User entered 'None (1)'	System	07 Sep 2020 23:10:45

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-07T19:10:35', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '67aab04b-de44-4087-a741-08f0a7589a32'	System	07 Sep 2020 23:10:45
User entered 'No (N)'	System	07 Sep 2020 23:10:45

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-07T19:10:39', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '67aab04b-de44-4087-a741-08f0a7589a32' User entered 'No (N)'	System	07 Sep 2020 23:10:45
	System	07 Sep 2020 23:10:45

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-07T19:10:40', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '67aab04b-de44-4087-a741-08f0a7589a32'	System	07 Sep 2020 23:10:45
User entered 'None (1)'	System	07 Sep 2020 23:10:45

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-07T19:10:43', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '67aab04b-de44-4087-a741-08f0a7589a32' User entered '07 Sep 2020 19:10'	System	07 Sep 2020 23:10:45
	System	07 Sep 2020 23:10:45

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	01 Sep 2020 15:26:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T11:30:23', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '0271e019-b9fb-4ffd-aa5f-7034c4d07117' User entered 'None (0)'	System	01 Sep 2020 15:30:48
	System	01 Sep 2020 15:30:48

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T11:30:26', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '0271e019-b9fb-4ffd-aa5f-7034c4d07117' User entered 'None (0)'	System	01 Sep 2020 15:30:48
	System	01 Sep 2020 15:30:48

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T11:30:31', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '0271e019-b9fb-4ffd-aa5f-7034c4d07117' User entered 'None (0)'	System	01 Sep 2020 15:30:48
	System	01 Sep 2020 15:30:48

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T11:30:35', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '0271e019-b9fb-4ffd-aa5f-7034c4d07117' User entered 'None (0)'	System	01 Sep 2020 15:30:48
	System	01 Sep 2020 15:30:48

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T11:30:38', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '0271e019-b9fb-4ffd-aa5f-7034c4d07117' User entered 'None (0)'	System	01 Sep 2020 15:30:48
	System	01 Sep 2020 15:30:48

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T11:30:41', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '0271e019-b9fb-4ffd-aa5f-7034c4d07117' User entered 'None (0)'	System	01 Sep 2020 15:30:48
	System	01 Sep 2020 15:30:48

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T11:30:44', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '0271e019-b9fb-4ffd-aa5f-7034c4d07117' User entered 'No (N)'	System	01 Sep 2020 15:30:48
	System	01 Sep 2020 15:30:48

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T11:30:46', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '0271e019-b9fb-4ffd-aa5f-7034c4d07117' User entered '01 Sep 2020 11:30'	System	01 Sep 2020 15:30:48
	System	01 Sep 2020 15:30:48

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '01 Sep 2020 11:16'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '01 Sep 2020 13:46'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	01 Sep 2020 15:26:14
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T19:06:12', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'add7941f-7343-4ff9-8b4c-4d82af1fed50' User entered 'None (0)'	System	01 Sep 2020 23:06:47
	System	01 Sep 2020 23:06:47

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T19:06:21', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'add7941f-7343-4ff9-8b4c-4d82af1fed50'	System	01 Sep 2020 23:06:47
User entered 'No interference with activity (1)'	System	01 Sep 2020 23:06:47

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T19:06:24', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'add7941f-7343-4ff9-8b4c-4d82af1fed50' User entered 'None (0)'	System	01 Sep 2020 23:06:47
	System	01 Sep 2020 23:06:47

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T19:06:26', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'add7941f-7343-4ff9-8b4c-4d82af1fed50' User entered 'None (0)'	System	01 Sep 2020 23:06:47
	System	01 Sep 2020 23:06:47

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T19:06:35', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'add7941f-7343-4ff9-8b4c-4d82af1fed50' User entered 'None (0)'	System	01 Sep 2020 23:06:47
	System	01 Sep 2020 23:06:47

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T19:06:38', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'add7941f-7343-4ff9-8b4c-4d82af1fed50'	System	01 Sep 2020 23:06:47
User entered 'No interference with activity (1)'	System	01 Sep 2020 23:06:47

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T19:06:42', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'add7941f-7343-4ff9-8b4c-4d82af1fed50'	System	01 Sep 2020 23:06:47
User entered 'No (N)'	System	01 Sep 2020 23:06:47

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-01T19:06:45', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'add7941f-7343-4ff9-8b4c-4d82af1fed50'	System	01 Sep 2020 23:06:47
User entered '01 Sep 2020 19:06'	System	01 Sep 2020 23:06:47

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '01 Sep 2020 14:41'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	01 Sep 2020 15:26:14
User entered 'Day 2'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-02T16:45:52', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '42242f0d-8e56-4876-8361-34eabf5babcf'	System	02 Sep 2020 20:46:26
User entered 'No interference with activity (1)'	System	02 Sep 2020 20:46:26

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-02T16:45:58', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '42242f0d-8e56-4876-8361-34eabf5babcf'	System	02 Sep 2020 20:46:26
User entered 'Some interference with activity (2)'	System	02 Sep 2020 20:46:26

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-02T16:46:01', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '42242f0d-8e56-4876-8361-34eabf5babcf' User entered 'None (0)'	System	02 Sep 2020 20:46:26
	System	02 Sep 2020 20:46:26

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-02T16:46:04', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '42242f0d-8e56-4876-8361-34eabf5babcf' User entered 'None (0)'	System	02 Sep 2020 20:46:26
	System	02 Sep 2020 20:46:26

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-02T16:46:08', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '42242f0d-8e56-4876-8361-34eabf5babcf' User entered 'None (0)'	System	02 Sep 2020 20:46:26
	System	02 Sep 2020 20:46:26

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-02T16:46:13', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '42242f0d-8e56-4876-8361-34eabf5babcf'	System	02 Sep 2020 20:46:26
User entered 'No interference with activity (1)'	System	02 Sep 2020 20:46:26

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-02T16:46:20', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '42242f0d-8e56-4876-8361-34eabf5babcf' User entered 'No (N)'	System	02 Sep 2020 20:46:26
	System	02 Sep 2020 20:46:26

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-02T16:46:24', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '42242f0d-8e56-4876-8361-34eabf5babcf' User entered '02 Sep 2020 16:46'	System	02 Sep 2020 20:46:26
	System	02 Sep 2020 20:46:26

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	01 Sep 2020 15:26:14
User entered 'Day 3'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-03T21:55:02', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '302140ae-ce61-4dbd-8c35-7c9b34906ab9' User entered 'None (0)'	System	04 Sep 2020 01:55:21
	System	04 Sep 2020 01:55:21

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-03T21:55:04', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '302140ae-ce61-4dbd-8c35-7c9b34906ab9' User entered 'None (0)'	System	04 Sep 2020 01:55:21
	System	04 Sep 2020 01:55:21

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-03T21:55:06', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '302140ae-ce61-4dbd-8c35-7c9b34906ab9' User entered 'None (0)'	System	04 Sep 2020 01:55:21
	System	04 Sep 2020 01:55:21

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-03T21:55:08', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '302140ae-ce61-4dbd-8c35-7c9b34906ab9' User entered 'None (0)'	System	04 Sep 2020 01:55:21
	System	04 Sep 2020 01:55:21

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-03T21:55:10', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '302140ae-ce61-4dbd-8c35-7c9b34906ab9' User entered 'None (0)'	System	04 Sep 2020 01:55:21
	System	04 Sep 2020 01:55:21

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-03T21:55:12', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '302140ae-ce61-4dbd-8c35-7c9b34906ab9' User entered 'None (0)'	System	04 Sep 2020 01:55:21
	System	04 Sep 2020 01:55:21

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-03T21:55:14', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '302140ae-ce61-4dbd-8c35-7c9b34906ab9' User entered 'No (N)'	System	04 Sep 2020 01:55:21
	System	04 Sep 2020 01:55:21

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-03T21:55:17', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '302140ae-ce61-4dbd-8c35-7c9b34906ab9' User entered '03 Sep 2020 21:55'	System	04 Sep 2020 01:55:21
	System	04 Sep 2020 01:55:21

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	01 Sep 2020 15:26:14
User entered 'Day 4'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-04T17:33:41', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '3ef4c9c2-a50d-4298-97c4-b5551fb8b880' User entered 'None (0)'	System	04 Sep 2020 21:33:56
	System	04 Sep 2020 21:33:56

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-04T17:33:44', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '3ef4c9c2-a50d-4298-97c4-b5551fb8b880' User entered 'None (0)'	System	04 Sep 2020 21:33:56
	System	04 Sep 2020 21:33:56

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-04T17:33:45', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '3ef4c9c2-a50d-4298-97c4-b5551fb8b880' User entered 'None (0)'	System	04 Sep 2020 21:33:56
	System	04 Sep 2020 21:33:56

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-04T17:33:47', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '3ef4c9c2-a50d-4298-97c4-b5551fb8b880' User entered 'None (0)'	System	04 Sep 2020 21:33:56
	System	04 Sep 2020 21:33:56

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-04T17:33:48', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '3ef4c9c2-a50d-4298-97c4-b5551fb8b880' User entered 'None (0)'	System	04 Sep 2020 21:33:56
	System	04 Sep 2020 21:33:56

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-04T17:33:50', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '3ef4c9c2-a50d-4298-97c4-b5551fb8b880' User entered 'None (0)'	System	04 Sep 2020 21:33:56
	System	04 Sep 2020 21:33:56

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-04T17:33:52', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '3ef4c9c2-a50d-4298-97c4-b5551fb8b880' User entered 'No (N)'	System	04 Sep 2020 21:33:56
	System	04 Sep 2020 21:33:56

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-04T17:33:54', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '3ef4c9c2-a50d-4298-97c4-b5551fb8b880' User entered '04 Sep 2020 17:33'	System	04 Sep 2020 21:33:56
	System	04 Sep 2020 21:33:56

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	01 Sep 2020 15:26:14
User entered 'Day 5'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-05T19:46:02', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '1149a226-c45c-41ba-a7e1-5e705e0828ae' User entered 'None (0)'	System	05 Sep 2020 23:46:26
	System	05 Sep 2020 23:46:26

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-05T19:46:04', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '1149a226-c45c-41ba-a7e1-5e705e0828ae' User entered 'None (0)'	System	05 Sep 2020 23:46:26
	System	05 Sep 2020 23:46:26

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-05T19:46:16', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '1149a226-c45c-41ba-a7e1-5e705e0828ae' User entered 'None (0)'	System	05 Sep 2020 23:46:26
	System	05 Sep 2020 23:46:26

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-05T19:46:14', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '1149a226-c45c-41ba-a7e1-5e705e0828ae' User entered 'None (0)'	System	05 Sep 2020 23:46:26
	System	05 Sep 2020 23:46:26

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-05T19:46:17', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '1149a226-c45c-41ba-a7e1-5e705e0828ae' User entered 'None (0)'	System	05 Sep 2020 23:46:26
	System	05 Sep 2020 23:46:26

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-05T19:46:19', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '1149a226-c45c-41ba-a7e1-5e705e0828ae' User entered 'None (0)'	System	05 Sep 2020 23:46:26
	System	05 Sep 2020 23:46:26

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-05T19:46:22', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '1149a226-c45c-41ba-a7e1-5e705e0828ae' User entered 'No (N)'	System	05 Sep 2020 23:46:26
	System	05 Sep 2020 23:46:26

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-05T19:46:25', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '1149a226-c45c-41ba-a7e1-5e705e0828ae' User entered '05 Sep 2020 19:46'	System	05 Sep 2020 23:46:26
	System	05 Sep 2020 23:46:26

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	01 Sep 2020 15:26:14
User entered 'Day 6'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-06T15:01:08', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4b8c0bfc-c7b0-4563-98d5-4b367c73fb0b' User entered 'None (0)'	System	06 Sep 2020 19:01:27
	System	06 Sep 2020 19:01:27

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-06T15:01:10', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4b8c0bfc-c7b0-4563-98d5-4b367c73fb0b' User entered 'None (0)'	System	06 Sep 2020 19:01:27
	System	06 Sep 2020 19:01:27

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-06T15:01:12', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4b8c0bfc-c7b0-4563-98d5-4b367c73fb0b' User entered 'None (0)'	System	06 Sep 2020 19:01:27
	System	06 Sep 2020 19:01:27

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-06T15:01:14', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4b8c0bfc-c7b0-4563-98d5-4b367c73fb0b' User entered 'None (0)'	System	06 Sep 2020 19:01:27
	System	06 Sep 2020 19:01:27

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-06T15:01:16', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4b8c0bfc-c7b0-4563-98d5-4b367c73fb0b' User entered 'None (0)'	System	06 Sep 2020 19:01:27
	System	06 Sep 2020 19:01:27

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-06T15:01:18', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4b8c0bfc-c7b0-4563-98d5-4b367c73fb0b' User entered 'None (0)'	System	06 Sep 2020 19:01:27
	System	06 Sep 2020 19:01:27

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-06T15:01:23', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4b8c0bfc-c7b0-4563-98d5-4b367c73fb0b' User entered 'No (N)'	System	06 Sep 2020 19:01:27
	System	06 Sep 2020 19:01:27

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-06T15:01:25', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4b8c0bfc-c7b0-4563-98d5-4b367c73fb0b' User entered '06 Sep 2020 15:01'	System	06 Sep 2020 19:01:27
	System	06 Sep 2020 19:01:27

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	01 Sep 2020 15:26:14
User entered 'Day 7'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-07T19:10:46', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '12addade-266f-4337-b293-5c71e587cdb0' User entered 'None (0)'	System	07 Sep 2020 23:12:50
	System	07 Sep 2020 23:12:50

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-07T19:10:48', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '12addade-266f-4337-b293-5c71e587cdb0' User entered 'None (0)'	System	07 Sep 2020 23:12:50
	System	07 Sep 2020 23:12:50

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-07T19:10:49', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '12addade-266f-4337-b293-5c71e587cdb0' User entered 'None (0)'	System	07 Sep 2020 23:12:50
	System	07 Sep 2020 23:12:50

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-07T19:10:51', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '12addade-266f-4337-b293-5c71e587cdb0' User entered 'None (0)'	System	07 Sep 2020 23:12:50
	System	07 Sep 2020 23:12:50

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-07T19:10:53', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '12addade-266f-4337-b293-5c71e587cdb0' User entered 'None (0)'	System	07 Sep 2020 23:12:50
	System	07 Sep 2020 23:12:50

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-07T19:11:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '12addade-266f-4337-b293-5c71e587cdb0' User entered 'None (0)'	System	07 Sep 2020 23:12:50
	System	07 Sep 2020 23:12:50

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-07T19:10:58', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '12addade-266f-4337-b293-5c71e587cdb0' User entered 'No (N)'	System	07 Sep 2020 23:12:50
	System	07 Sep 2020 23:12:50

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-09-07T19:12:47', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '12addade-266f-4337-b293-5c71e587cdb0' User entered '07 Sep 2020 19:12'	System	07 Sep 2020 23:12:50
	System	07 Sep 2020 23:12:50

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 15:26:14

US3822003

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 15:26:14

US3822003

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Sep 2020 15:11:05

US3822003

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '9 Sep 2020'	Krishna Shah (b) (4)	28 Sep 2020 15:11:05

US3822003

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Contact Made (CONTACT MADE)'	Krishna Shah (b) (4)	28 Sep 2020 15:11:05

US3822003

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered empty.	(b) (4) Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:11:05

US3822003

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Sep 2020 15:11:16

US3822003

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'I'	System	28 Sep 2020 15:11:16

US3822003

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Sep 2020 15:17:41

US3822003

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '16 Sep 2020'	Krishna Shah (b) (4)	28 Sep 2020 15:17:41

US3822003

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Contact Made (CONTACT MADE)'	Krishna Shah (b) (4)	28 Sep 2020 15:17:41

US3822003

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered empty.	(b) (4) Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:17:41

US3822003

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Sep 2020 15:17:46

US3822003

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'I'	System	28 Sep 2020 15:17:46

US3822003

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Sep 2020 15:18:28

US3822003

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered '23 Sep 2020'	Krishna Shah (b) (4)	28 Sep 2020 15:18:28

US3822003

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Contact Made (CONTACT MADE)'	Krishna Shah (b) (4)	28 Sep 2020 15:18:28

US3822003

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered empty.	(b) (4) Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:18:28

US3822003

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:01:41
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Sep 2020 15:21:07

US3822003

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'I'	System	28 Sep 2020 15:21:07

US3822003

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:08:52

US3822003

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:08:52

US3822003

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:59

[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 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:08:52

US3822003

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'VISIT3'	System	04 Oct 2020 22:08:52

US3822003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:09:51

US3822003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:09:51

US3822003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '09:49'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:09:51

US3822003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered '29 Sep 2020 09:49'	System	04 Oct 2020 22:09:51

US3822003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:09:51

US3822003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:09:51

US3822003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:09:51

US3822003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '52'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:09:51

US3822003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'bpm'	System	04 Oct 2020 22:09:51

US3822003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '12'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:09:51

US3822003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'breaths/min'	System	04 Oct 2020 22:09:51

US3822003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '130'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:09:51

US3822003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'mmHg'	System	04 Oct 2020 22:09:51

US3822003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '82'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:09:51

US3822003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'mmHg'	System	04 Oct 2020 22:09:51

US3822003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24

US3822003

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24

US3822003

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:10:13

US3822003

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:10:13

US3822003

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:10:30

US3822003

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:10:30

US3822003

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered '09:58'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:10:30

US3822003

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered '29 Sep 2020 09:58'	System	04 Oct 2020 22:10:30

US3822003

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:02:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:02:57

US3822003

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'I'	System	29 Sep 2020 14:02:57

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 64'	System	04 Aug 2020 15:35:22

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-10-06T07:31:25', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'ba99d800-331a-4b86-a872-bd3248ee9851'	System	06 Oct 2020 11:31:49
User entered 'No (N)'	System	06 Oct 2020 11:31:49

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you been exposed to someone with 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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-10-06T07:31:35', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'ba99d800-331a-4b86-a872-bd3248ee9851'	System	06 Oct 2020 11:31:49
User entered 'No (N)'	System	06 Oct 2020 11:31:49

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-10-06T07:31:42', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'ba99d800-331a-4b86-a872-bd3248ee9851' User entered '06 Oct 2020 07:31:42'	System	06 Oct 2020 11:31:49
	System	06 Oct 2020 11:31:49

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered '04 Oct 2020 00:01'	System	04 Aug 2020 15:35:22

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered '08 Oct 2020 23:59'	System	04 Aug 2020 15:35:22

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 71'	System	04 Aug 2020 15:35:22

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-10-11T17:22:59', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c364630b-d7bb-4ab0-b745-ad7db4d3b58b'	System	11 Oct 2020 21:23:18
User entered 'No (N)'	System	11 Oct 2020 21:23:18

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you been exposed to someone with 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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-10-11T17:23:12', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c364630b-d7bb-4ab0-b745-ad7db4d3b58b'	System	11 Oct 2020 21:23:18
User entered 'No (N)'	System	11 Oct 2020 21:23:18

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-10-11T17:23:15', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c364630b-d7bb-4ab0-b745-ad7db4d3b58b' User entered '11 Oct 2020 17:23:15'	System	11 Oct 2020 21:23:18
	System	11 Oct 2020 21:23:18

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered '11 Oct 2020 00:01'	System	04 Aug 2020 15:35:22

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered '15 Oct 2020 23:59'	System	04 Aug 2020 15:35:22

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 78'	System	04 Aug 2020 15:35:22

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-10-18T09:30:18', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '6d1d58e3-10f8-47f4-a606-8556ab321289'	System	18 Oct 2020 13:30:30
User entered 'No (N)'	System	18 Oct 2020 13:30:30

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you been exposed to someone with 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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-10-18T09:30:24', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '6d1d58e3-10f8-47f4-a606-8556ab321289'	System	18 Oct 2020 13:30:30
User entered 'No (N)'	System	18 Oct 2020 13:30:30

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-10-18T09:30:28', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '6d1d58e3-10f8-47f4-a606-8556ab321289' User entered '18 Oct 2020 09:30:28'	System	18 Oct 2020 13:30:30
	System	18 Oct 2020 13:30:30

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered '18 Oct 2020 00:01'	System	04 Aug 2020 15:35:22

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered '22 Oct 2020 23:59'	System	04 Aug 2020 15:35:22

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 92'	System	04 Aug 2020 15:35:22

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-11-05T06:35:39', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4dd8efce-f11c-44e5-b6c1-6f2eb4de668f' User entered 'Yes (Y)'	System	05 Nov 2020 11:36:23
	System	05 Nov 2020 11:36:23

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you been exposed to someone with 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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-11-05T06:35:45', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4dd8efce-f11c-44e5-b6c1-6f2eb4de668f' User entered 'No (N)'	System	05 Nov 2020 11:36:23
	System	05 Nov 2020 11:36:23

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-11-05T06:35:50', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4dd8efce-f11c-44e5-b6c1-6f2eb4de668f' User entered 'No (N)'	System	05 Nov 2020 11:36:23
	System	05 Nov 2020 11:36:23

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-11-05T06:36:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4dd8efce-f11c-44e5-b6c1-6f2eb4de668f' User entered 'Yes (Y)'	System	05 Nov 2020 11:36:23
	System	05 Nov 2020 11:36:23

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-11-05T06:36:06', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4dd8efce-f11c-44e5-b6c1-6f2eb4de668f'	System	05 Nov 2020 11:36:23
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Nov 2020 11:36:23

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-11-05T06:36:12', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4dd8efce-f11c-44e5-b6c1-6f2eb4de668f' User entered '05 Nov 2020 06:36:12'	System	05 Nov 2020 11:36:23
	System	05 Nov 2020 11:36:23

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered '01 Nov 2020 00:01'	System	04 Aug 2020 15:35:22

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered '05 Nov 2020 23:59'	System	04 Aug 2020 15:35:22

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 99'	System	04 Aug 2020 15:35:22

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-11-10T22:24:33', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '7d2fc9f9-f241-4aaf-9190-4e4da5e63f5d'	System	11 Nov 2020 03:25:02
User entered 'No (N)'	System	11 Nov 2020 03:25:02

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you been exposed to someone with 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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-11-10T22:24:55', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '7d2fc9f9-f241-4aaf-9190-4e4da5e63f5d'	System	11 Nov 2020 03:25:02
User entered 'No (N)'	System	11 Nov 2020 03:25:02

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-11-10T22:24:59', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '7d2fc9f9-f241-4aaf-9190-4e4da5e63f5d' User entered '10 Nov 2020 22:24:59'	System	11 Nov 2020 03:25:02
	System	11 Nov 2020 03:25:02

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered '08 Nov 2020 00:01'	System	04 Aug 2020 15:35:22

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered '12 Nov 2020 23:59'	System	04 Aug 2020 15:35:22

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered 'Day 106'	System	04 Aug 2020 15:35:22

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-11-15T19:34:33', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'a1d44f57-5580-42c3-b2af-9308116f81f5'	System	16 Nov 2020 00:35:12
User entered 'Yes (Y)'	System	16 Nov 2020 00:35:12

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you been exposed to someone with 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 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-11-15T19:34:30', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'a1d44f57-5580-42c3-b2af-9308116f81f5'	System	16 Nov 2020 00:35:12
User entered 'No (N)'	System	16 Nov 2020 00:35:12

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-11-15T19:34:39', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'a1d44f57-5580-42c3-b2af-9308116f81f5'	System	16 Nov 2020 00:35:12
User entered 'No (N)'	System	16 Nov 2020 00:35:12

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-11-15T19:34:44', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'a1d44f57-5580-42c3-b2af-9308116f81f5'	System	16 Nov 2020 00:35:12
User entered 'Yes (Y)'	System	16 Nov 2020 00:35:12

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-11-15T19:34:58', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'a1d44f57-5580-42c3-b2af-9308116f81f5'	System	16 Nov 2020 00:35:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Nov 2020 00:35:12

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-11-15T19:35:02', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'a1d44f57-5580-42c3-b2af-9308116f81f5' User entered '15 Nov 2020 19:35:02'	System	16 Nov 2020 00:35:12
	System	16 Nov 2020 00:35:12

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered '15 Nov 2020 00:01'	System	04 Aug 2020 15:35:22

US3822003

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:53
Data entry locked.	System	04 Aug 2020 15:35:22
User entered '19 Nov 2020 23:59'	System	04 Aug 2020 15:35:22

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-11-21T10:07:32', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '735ad8f9-7319-495f-8a6c-9eb020c29027'	System	21 Nov 2020 15:07:44
User entered 'No (N)'	System	21 Nov 2020 15:07:44

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you been exposed to someone with 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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-11-21T10:07:37', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '735ad8f9-7319-495f-8a6c-9eb020c29027'	System	21 Nov 2020 15:07:44
User entered 'No (N)'	System	21 Nov 2020 15:07:44

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-11-21T10:07:42', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '735ad8f9-7319-495f-8a6c-9eb020c29027' User entered '21 Nov 2020 10:07:42'	System	21 Nov 2020 15:07:44
	System	21 Nov 2020 15:07:44

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-11-28T08:10:53', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '82560489-e54d-4890-8e5b-0dbb2b7ee6fc' User entered 'No (N)'	System	28 Nov 2020 13:11:03
	System	28 Nov 2020 13:11:03

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you been exposed to someone with 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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-11-28T08:10:55', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '82560489-e54d-4890-8e5b-0dbb2b7ee6fc'	System	28 Nov 2020 13:11:03
User entered 'No (N)'	System	28 Nov 2020 13:11:03

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-11-28T08:10:58', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '82560489-e54d-4890-8e5b-0dbb2b7ee6fc' User entered '28 Nov 2020 08:10:58'	System	28 Nov 2020 13:11:03
	System	28 Nov 2020 13:11:03

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-12-03T11:16:28', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4b318a07-e481-4aed-8654-1551d7ebc391'	System	03 Dec 2020 16:16:48
User entered 'No (N)'	System	03 Dec 2020 16:16:48

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you been exposed to someone with 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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-12-03T11:16:42', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4b318a07-e481-4aed-8654-1551d7ebc391'	System	03 Dec 2020 16:16:48
User entered 'No (N)'	System	03 Dec 2020 16:16:48

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-12-03T11:16:45', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4b318a07-e481-4aed-8654-1551d7ebc391' User entered '03 Dec 2020 11:16:45'	System	03 Dec 2020 16:16:48
	System	03 Dec 2020 16:16:48

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-12-10T16:25:24', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '65e49288-7a6e-40dd-b0ad-47ec3e8b38d8' User entered 'No (N)'	System	10 Dec 2020 21:25:41
	System	10 Dec 2020 21:25:41

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you been exposed to someone with 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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-12-10T16:25:32', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '65e49288-7a6e-40dd-b0ad-47ec3e8b38d8' User entered 'No (N)'	System	10 Dec 2020 21:25:41
	System	10 Dec 2020 21:25:41

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-12-10T16:25:39', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '65e49288-7a6e-40dd-b0ad-47ec3e8b38d8' User entered '10 Dec 2020 16:25:39'	System	10 Dec 2020 21:25:41
	System	10 Dec 2020 21:25:41

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-12-17T06:24:47', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '6926e1a7-4e92-4040-af95-c989953ecd89' User entered 'No (N)'	System	17 Dec 2020 11:25:05
	System	17 Dec 2020 11:25:05

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you been exposed to someone with 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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-12-17T06:24:58', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '6926e1a7-4e92-4040-af95-c989953ecd89' User entered 'No (N)'	System	17 Dec 2020 11:25:05
	System	17 Dec 2020 11:25:05

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-12-17T06:25:01', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '6926e1a7-4e92-4040-af95-c989953ecd89' User entered '17 Dec 2020 06:25:01'	System	17 Dec 2020 11:25:05
	System	17 Dec 2020 11:25:05

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-12-25T08:06:23', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '692f2136-0024-4532-a094-13d308efd178' User entered 'No (N)'	System	25 Dec 2020 13:06:37
	System	25 Dec 2020 13:06:37

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you been exposed to someone with 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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-12-25T08:06:30', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '692f2136-0024-4532-a094-13d308efd178' User entered 'No (N)'	System	25 Dec 2020 13:06:37
	System	25 Dec 2020 13:06:37

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-12-25T08:06:33', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '692f2136-0024-4532-a094-13d308efd178' User entered '25 Dec 2020 08:06:33'	System	25 Dec 2020 13:06:37
	System	25 Dec 2020 13:06:37

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-12-31T14:35:11', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '8558a709-d463-41f8-b477-0194f7a9b575' User entered 'No (N)'	System	31 Dec 2020 19:35:28
	System	31 Dec 2020 19:35:28

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you been exposed to someone with 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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-12-31T14:35:22', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '8558a709-d463-41f8-b477-0194f7a9b575'	System	31 Dec 2020 19:35:28
User entered 'No (N)'	System	31 Dec 2020 19:35:28

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2020-12-31T14:35:25', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '8558a709-d463-41f8-b477-0194f7a9b575' User entered '31 Dec 2020 14:35:25'	System	31 Dec 2020 19:35:28
	System	31 Dec 2020 19:35:28

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-01-07T15:05:58', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c2a42791-d3c6-480c-acb0-f0f2fc281b25'	System	07 Jan 2021 20:06:12
User entered 'No (N)'	System	07 Jan 2021 20:06:12

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you been exposed to someone with 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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-01-07T15:06:04', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c2a42791-d3c6-480c-acb0-f0f2fc281b25'	System	07 Jan 2021 20:06:12
User entered 'No (N)'	System	07 Jan 2021 20:06:12

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-01-07T15:06:09', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c2a42791-d3c6-480c-acb0-f0f2fc281b25' User entered '07 Jan 2021 15:06:09'	System	07 Jan 2021 20:06:12
	System	07 Jan 2021 20:06:12

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-01-15T22:53:57', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c5a4ea3b-5b2b-46ff-82b1-03c88cdabbf5'	System	16 Jan 2021 03:54:18
User entered 'No (N)'	System	16 Jan 2021 03:54:18

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you been exposed to someone with 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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-01-15T22:54:10', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c5a4ea3b-5b2b-46ff-82b1-03c88cdabbf5'	System	16 Jan 2021 03:54:18
User entered 'No (N)'	System	16 Jan 2021 03:54:18

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-01-15T22:54:15', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c5a4ea3b-5b2b-46ff-82b1-03c88cdabbf5'	System	16 Jan 2021 03:54:18
User entered '15 Jan 2021 22:54:15'	System	16 Jan 2021 03:54:18

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-01-21T08:57:20', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '219758d8-3b90-4872-afc3-d40bdd454a64'	System	21 Jan 2021 13:57:35
User entered 'No (N)'	System	21 Jan 2021 13:57:35

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you been exposed to someone with 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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-01-21T08:57:26', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '219758d8-3b90-4872-afc3-d40bdd454a64'	System	21 Jan 2021 13:57:35
User entered 'No (N)'	System	21 Jan 2021 13:57:35

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-01-21T08:57:29', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '219758d8-3b90-4872-afc3-d40bdd454a64' User entered '21 Jan 2021 08:57:29'	System	21 Jan 2021 13:57:35

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-01-28T09:12:34', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'eac3d5c6-3756-4048-a8ea-345e75d050e0' User entered 'No (N)'	System	04 Feb 2021 16:08:35
	System	04 Feb 2021 16:08:35

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you been exposed to someone with 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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-01-28T09:12:38', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'eac3d5c6-3756-4048-a8ea-345e75d050e0' User entered 'No (N)'	System	04 Feb 2021 16:08:35

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-01-28T09:12:44', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'eac3d5c6-3756-4048-a8ea-345e75d050e0' User entered '28 Jan 2021 09:12:44'	System	04 Feb 2021 16:08:35
	System	04 Feb 2021 16:08:35

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-02-04T11:08:37', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c1ea6e74-4c78-452e-8178-4ace7d9ff4ef' User entered 'No (N)'	System	04 Feb 2021 16:08:58

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you been exposed to someone with 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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-02-04T11:08:40', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c1ea6e74-4c78-452e-8178-4ace7d9ff4ef' User entered 'No (N)'	System	04 Feb 2021 16:08:58

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-02-04T11:08:43', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c1ea6e74-4c78-452e-8178-4ace7d9ff4ef' User entered '04 Feb 2021 11:08:43'	System	04 Feb 2021 16:08:58
	System	04 Feb 2021 16:08:58

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-02-20T09:05:37', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4b3b981d-e54b-4f88-a165-52b56d4c73a3' User entered 'No (N)'	System	20 Feb 2021 14:05:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you been exposed to someone with 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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-02-20T09:05:45', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4b3b981d-e54b-4f88-a165-52b56d4c73a3'	System	20 Feb 2021 14:05:51
User entered 'No (N)'	System	20 Feb 2021 14:05:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-02-20T09:05:48', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '4b3b981d-e54b-4f88-a165-52b56d4c73a3' User entered '20 Feb 2021 09:05:48'	System	20 Feb 2021 14:05:51
	System	20 Feb 2021 14:05:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-02-25T20:07:27-05:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c9150066-f90e-471c-bab4-29d900b37f05'	System	26 Feb 2021 01:09:53
User entered 'No (N)'	System	26 Feb 2021 01:09:53

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you been exposed to someone with 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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-02-25T20:07:29-05:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c9150066-f90e-471c-bab4-29d900b37f05'	System	26 Feb 2021 01:09:53
User entered 'No (N)'	System	26 Feb 2021 01:09:53

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-02-25T20:07:32-05:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'c9150066-f90e-471c-bab4-29d900b37f05' User entered '26 Feb 2021 01:07:32'	System	26 Feb 2021 01:09:53
	System	26 Feb 2021 01:09:53

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-03-05T20:19:21-05:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '79aab9d2-e307-4fa3-9e7d-9b3e805b6393'	System	06 Mar 2021 01:19:38
User entered 'No (N)'	System	06 Mar 2021 01:19:38

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you been exposed to someone with 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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-03-05T20:19:23-05:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '79aab9d2-e307-4fa3-9e7d-9b3e805b6393'	System	06 Mar 2021 01:19:38
User entered 'No (N)'	System	06 Mar 2021 01:19:38

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-03-05T20:19:31-05:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '79aab9d2-e307-4fa3-9e7d-9b3e805b6393' User entered '05 Mar 2021 20:19:31'	System	06 Mar 2021 01:19:38
	System	06 Mar 2021 01:19:38

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-03-11T10:54:37-05:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'ada84ba5-ea4f-4851-aaf3-1a83bbfc0ab9'	System	15 Mar 2021 18:48:29
User entered 'No (N)'	System	15 Mar 2021 18:48:29

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you been exposed to someone with 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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-03-11T10:54:47-05:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'ada84ba5-ea4f-4851-aaf3-1a83bbfc0ab9' User entered 'No (N)'	System	15 Mar 2021 18:48:29

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-03-11T10:54:51-05:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'ada84ba5-ea4f-4851-aaf3-1a83bbfc0ab9' User entered '11 Mar 2021 10:54:51'	System	15 Mar 2021 18:48:29

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-03-18T14:49:30-04:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '1813796c-c5d5-4efc-bc73-436c615c8532'	System	21 Mar 2021 17:49:49
User entered 'No (N)'	System	21 Mar 2021 17:49:49

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you been exposed to someone with 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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-03-18T14:49:33-04:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '1813796c-c5d5-4efc-bc73-436c615c8532'	System	21 Mar 2021 17:49:49
User entered 'No (N)'	System	21 Mar 2021 17:49:49

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-03-18T14:49:39-04:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '1813796c-c5d5-4efc-bc73-436c615c8532'	System	21 Mar 2021 17:49:49
User entered '18 Mar 2021 14:49:39'	System	21 Mar 2021 17:49:49

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-03-25T12:24:18-04:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '66a35499-760f-4dd0-925a-741568c247f1'	System	25 Mar 2021 16:27:20
User entered 'No (N)'	System	25 Mar 2021 16:27:20

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Have you been exposed to someone with 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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-03-25T12:24:20-04:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '66a35499-760f-4dd0-925a-741568c247f1'	System	25 Mar 2021 16:27:20
User entered 'No (N)'	System	25 Mar 2021 16:27:20

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-03-25T12:24:22-04:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '66a35499-760f-4dd0-925a-741568c247f1' User entered '25 Mar 2021 12:24:22'	System	25 Mar 2021 16:27:20
	System	25 Mar 2021 16:27:20

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-04-01T11:45:33-04:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'ae8bf18d-9614-4ef9-b465-c63736670ce9' User entered 'No (N)'	System	01 Apr 2021 15:45:41

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Have you been exposed to someone with 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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-04-01T11:45:35-04:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'ae8bf18d-9614-4ef9-b465-c63736670ce9' User entered 'No (N)'	System	01 Apr 2021 15:45:41

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-04-01T11:45:38-04:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'ae8bf18d-9614-4ef9-b465-c63736670ce9' User entered '01 Apr 2021 11:45:38'	System	01 Apr 2021 15:45:41
	System	01 Apr 2021 15:45:41

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-04-08T12:24:16-04:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'aba9d8b9-d735-487a-8329-65aa3ad09427'	System	08 Apr 2021 16:24:29
User entered 'No (N)'	System	08 Apr 2021 16:24:29

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you been exposed to someone with 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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-04-08T12:24:22-04:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'aba9d8b9-d735-487a-8329-65aa3ad09427'	System	08 Apr 2021 16:24:29
User entered 'No (N)'	System	08 Apr 2021 16:24:29

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-04-08T12:24:26-04:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'aba9d8b9-d735-487a-8329-65aa3ad09427'	System	08 Apr 2021 16:24:29
User entered '08 Apr 2021 12:24:26'	System	08 Apr 2021 16:24:29

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-04-18T17:09:45-04:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '9fa73e38-1b4a-47c9-9920-09e0f97b6899'	System	18 Apr 2021 21:10:06
User entered 'No (N)'	System	18 Apr 2021 21:10:06

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you been exposed to someone with 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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-04-18T17:09:59-04:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '9fa73e38-1b4a-47c9-9920-09e0f97b6899' User entered 'No (N)'	System	18 Apr 2021 21:10:06
	System	18 Apr 2021 21:10:06

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-04-18T17:10:02-04:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '9fa73e38-1b4a-47c9-9920-09e0f97b6899'	System	18 Apr 2021 21:10:06
User entered '18 Apr 2021 17:10:02'	System	18 Apr 2021 21:10:06

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-04-22T14:20:40-04:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'ad80eb21-697d-4b71-a1ad-127fa57dcf9a'	System	22 Apr 2021 18:20:53
User entered 'No (N)'	System	22 Apr 2021 18:20:53

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you been exposed to someone with 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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-04-22T14:20:48-04:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'ad80eb21-697d-4b71-a1ad-127fa57dcf9a'	System	22 Apr 2021 18:20:53
User entered 'No (N)'	System	22 Apr 2021 18:20:53

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-04-22T14:20:51-04:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'ad80eb21-697d-4b71-a1ad-127fa57dcf9a'	System	22 Apr 2021 18:20:53
User entered '22 Apr 2021 14:20:51'	System	22 Apr 2021 18:20:53

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-04-29T10:46:13-04:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '605b5f23-d137-4d45-8e77-4289d9f3d308'	System	29 Apr 2021 15:12:59
User entered 'No (N)'	System	29 Apr 2021 15:12:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

Have you been exposed to someone with 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 (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-04-29T10:46:16-04:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '605b5f23-d137-4d45-8e77-4289d9f3d308'	System	29 Apr 2021 15:12:59
User entered 'No (N)'	System	29 Apr 2021 15:12:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-04-29T10:46:20-04:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: '605b5f23-d137-4d45-8e77-4289d9f3d308'	System	29 Apr 2021 15:12:59
User entered '29 Apr 2021 10:46:20'	System	29 Apr 2021 15:12:59

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 12:26:51

US3822003

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:26:51
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 12:26:51

US3822003

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:00:59

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 18:20:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-03-31T13:54:20-04:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'a7a6bdf7-6bd1-4d8f-9de1-e2542c911dcb'	System	31 Mar 2021 17:54:27
User entered 'No (N)'	System	31 Mar 2021 17:54:27

US3822003

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:00:59

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:20:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B95C9AFD-227C-41D4-96E2-0B770F2CA894)', Time: '2021-03-31T13:54:25-04:00', User OID: 'PatientReportedOutcome (US3822003)', ODM File OID: 'a7a6bdf7-6bd1-4d8f-9de1-e2542c911dcb' User entered '31 Mar 2021 13:54:25'	System	31 Mar 2021 17:54:27
	System	31 Mar 2021 17:54:27

US3822003

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:04:59
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Oct 2020 16:38:58

US3822003

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:04:59
User entered '27 Oct 2020'	Krishna Shah (b) (4)	28 Oct 2020 16:38:58

US3822003

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:04:59
User entered 'Contact Made (CONTACT MADE)'	Krishna Shah (b) (4)	28 Oct 2020 16:38:58

US3822003

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:04:59
User entered empty.	Krishna Shah (b) (4)	28 Oct 2020 16:38:58

US3822003

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:04:59
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Oct 2020 16:39:05

US3822003

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:31:24
User entered 'I'	System	28 Oct 2020 16:39:05

US3822003

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 19:50:22

US3822003

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered '24 Nov 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 19:50:22

US3822003

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 19:50:22

US3822003

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 19:50:22

US3822003

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 19:50:27

US3822003

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User entered 'I'	System	04 Jan 2021 19:50:27

US3822003

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 19:50:51

US3822003

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered '29 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 19:50:51

US3822003

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 19:50:51

US3822003

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 19:50:51

US3822003

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 19:50:55

US3822003

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User entered 'I'	System	04 Jan 2021 19:50:55

US3822003

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:16:23

US3822003

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:51:45
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Safety call completed one day out of window. Deviation noted.' (Site from System).	(b) (4), (b) (6)	03 Feb 2021 21:22:03
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	03 Feb 2021 20:16:23
User entered '02 Feb 2021'	(b) (4), (b) (6)	03 Feb 2021 20:16:23

US3822003

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:16:23

US3822003

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:16:23

US3822003

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:17:35

US3822003

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User entered 'I'	System	03 Feb 2021 20:17:35

US3822003

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 12:28:59

US3822003

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: PPD has 23FEB2021 Immuno sample labelled as Visit 4 which is missing in EDC. Please review if immuno sample was collected on 23-FEB-2021 then update the Immunogenicity form, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 05:44:55
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: PPD has 23FEB2021 Immuno sample labelled as Visit 4 which is missing in EDC. Please review if immuno sample was collected on 23-FEB-2021 then update the Immunogenicity form, else clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 12:17:30
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: PPD has 23FEB2021 Immuno sample labelled as Visit 4 which is missing in EDC. Please review if immuno sample was collected on 23-FEB-2021 then update the Immunogenicity form, else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 06:21:37
User entered '23 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 12:28:59

US3822003

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 12:28:59

US3822003

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User entered 'VISIT4'	System	26 Feb 2021 12:28:59

US3822003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:59:53

US3822003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:59:53

US3822003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:59:53

US3822003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User entered empty.	System	01 Apr 2021 14:59:53

US3822003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:59:53

US3822003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:59:53

US3822003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:59:53

US3822003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:59:53

US3822003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User entered empty.	System	01 Apr 2021 14:59:53

US3822003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:59:53

US3822003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User entered empty.	System	01 Apr 2021 14:59:53

US3822003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:59:53

US3822003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User entered empty.	System	01 Apr 2021 14:59:53

US3822003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:59:53

US3822003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User entered empty.	System	01 Apr 2021 14:59:53

US3822003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11

US3822003

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11

US3822003

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 12:29:17

US3822003

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 12:29:17

US3822003

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 12:17:22

US3822003

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 12:17:22

US3822003

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered '09:54'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 12:17:22

US3822003

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User entered '23 Feb 2021 09:54'	System	09 Mar 2021 12:17:22

US3822003

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 12:29:37

US3822003

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:36:11
User entered 'I'	System	26 Feb 2021 12:29:37

US3822003

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:48
User signature succeeded.	Christina Kennelly (b) (4)	11 Apr 2021 23:55:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:24:37

US3822003

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:48
User signature succeeded.	Christina Kennelly (b) (4)	11 Apr 2021 23:55:10
User entered '31 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:24:37

US3822003

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:48
User signature succeeded.	Christina Kennelly (b) (4)	11 Apr 2021 23:55:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:24:37

US3822003

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:48
User signature succeeded.	Christina Kennelly (b) (4)	11 Apr 2021 23:55:10
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:24:37

US3822003

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:48
User signature succeeded.	Christina Kennelly (b) (4)	11 Apr 2021 23:55:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:24:40

US3822003

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:48
User entered 'I'	System	05 Apr 2021 13:24:40

US3822003

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

Form: Visit Date

Generated On: 10 Jun 2021 10:00:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:28
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	05 Jan 2021 13:45:50

US3822003

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

Form: Visit Date

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:28
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered '4 Jan 2021'	Kelly Woodell (b) (4)	05 Jan 2021 13:45:50

US3822003

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

Form: Visit Date

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:28
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4)	05 Jan 2021 13:45:50

US3822003

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

Form: Visit Date

Generated On: 10 Jun 2021 10:00:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:28
User entered 'UNBLND_DECIDE'	System	05 Jan 2021 13:45:50

US3822003

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

Form: Unblinding

Generated On: 10 Jun 2021 10:00:59

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:28
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered '4 Jan 2021'	Kelly Woodell (b) (4)	05 Jan 2021 13:46:03

US3822003

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

Form: Unblinding

Generated On: 10 Jun 2021 10:00:59

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:28
User signature succeeded.	Christina Kennelly (b) (4)	11 Apr 2021 23:55:10
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 12:59:39
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:15:29

US3822003

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

Form: Unblinding

Generated On: 10 Jun 2021 10:00:59

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:28
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	05 Jan 2021 13:46:03

US3822003

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

Form: Unblinding

Generated On: 10 Jun 2021 10:00:59

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:28
User closed query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 05:45:57
User signature succeeded.	Christina Kennelly (b) (4)	11 Apr 2021 23:55:10
Query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 12:59:56
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	08 Apr 2021 12:59:39
User opened query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:39:24
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:15:29

US3822003

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

Form: Unblinding

Generated On: 10 Jun 2021 10:00:59

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:28
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered '4 Jan 2021'	Kelly Woodell (b) (4)	05 Jan 2021 13:46:03

US3822003

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

Form: Unblinding

Generated On: 10 Jun 2021 10:00:59

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:28
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered 'mRNA-1273 (mRNA-1273)'	Kelly Woodell (b) (4)	05 Jan 2021 13:46:03

US3822003

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

Form: Unblinding

Generated On: 10 Jun 2021 10:00:59

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:28
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 11:16:51
User entered 'mRNA-1273 (mRNA-1273)'	Kelly Woodell (b) (4)	05 Jan 2021 13:46:03
	(b) (4)	

US3822003

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

Form: Unblinding

Generated On: 10 Jun 2021 10:00:59

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:28
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 11:16:51
User entered 'mRNA-1273 (mRNA-1273)'	Kelly Woodell (b) (4)	05 Jan 2021 13:46:03
	(b) (4)	

US3822003

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

Form: Unblinding

Generated On: 10 Jun 2021 10:00:59

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:28
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered 'No (N)'	Kelly Woodell (b) (4)	05 Jan 2021 13:46:03

US3822003

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

Form: Unblinding

Generated On: 10 Jun 2021 10:00:59

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:28
User entered empty.	System	05 Jan 2021 13:46:03

US3822003

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

Form: Unblinding

Generated On: 10 Jun 2021 10:00:59

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:28
User entered empty.	System	05 Jan 2021 13:46:03

US3822003

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:28
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	05 Jan 2021 13:46:16

US3822003

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:28
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 04JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 04JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 13:35:39
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 04JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 04JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 19:45:58
User entered '4 Jan 2021'	Kelly Woodell (b) (4) (b) (4)	05 Jan 2021 13:46:16

US3822003

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:28
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered '15:27'	Kelly Woodell (b) (4)	05 Jan 2021 13:46:16

US3822003

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:28
User entered '4 Jan 2021 15:27'	System	05 Jan 2021 13:46:16

US3822003

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:00:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:28
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	05 Jan 2021 13:46:30

US3822003

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:28
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered '4 Jan 2021'	Kelly Woodell (b) (4)	05 Jan 2021 13:46:30

US3822003

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:00:59

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:28
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered '15:57'	Kelly Woodell (b) (4)	05 Jan 2021 13:46:30

US3822003

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:00:59

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:28
User entered '4 Jan 2021 15:57'	System	05 Jan 2021 13:46:30

US3822003

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:00:59

[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 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:15:44
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:12:01

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:16:12
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Urticarial rash - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 12:00:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 12:00:30
User closed query 'Per DM CLR: Please review AE and please update to specify the type of Rash (e.g. Maculopapular, Pustular, etc.) and if its URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 08:45:41
Data point term sent to Coder	System	04 Nov 2020 16:53:26
Query 'Per DM CLR: Please review AE and please update to specify the type of Rash (e.g. Maculopapular, Pustular, etc.) and if its URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'updated' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	04 Nov 2020 16:53:04
Coding entries removed.	Kelly Woodell (b) (4) (b) (4)	04 Nov 2020 16:52:55
User entered 'urticarial rash (Right arm)' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	04 Nov 2020 16:52:55
User opened query 'Per DM CLR: Please review AE and please update to specify the type of Rash (e.g. Maculopapular, Pustular, etc.) and if its URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 01:24:39

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Rash - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 18:01:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 18:01:43
Data point term sent to Coder	System	28 Sep 2020 15:16:06
User entered 'Growing rash on right arm'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:16:32
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:16:37
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:16:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:16:52
User entered '16 Sep 2020'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:45:34
Query 'Per CRIO source, start time is noted as 14:00. Please reconcile and update if applicable.' canceled (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 04:25:23
User opened query 'Per CRIO source, start time is noted as 14:00. Please reconcile and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 17:17:34
User closed query 'Start time is present for an AE thatSystem did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).		28 Sep 2020 15:17:05
User entered empty; reason for change Data Entry Error	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:17:05
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	28 Sep 2020 15:15:56
User entered '14:00'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User entered empty.	System	28 Sep 2020 15:17:05
User entered '16 Sep 2020 14:00'	System	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 22:11:52
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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 12:34:25
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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' answered with 'updated' (Site from DM).	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 20:29:36
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 20:29:27
User entered 'No (N)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 20:29:27
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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 03:26:07
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:17:40
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 22:11:54
User closed query 'Unable to locate this end date in EMR, kindly provide source. ' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 22:11:47
Query 'Unable to locate this end date in EMR, kindly provide source. ' answered with 'Please see progress note under subject level in CRIO. ' (Site from CRA).	Krishna Shah (b) (4) (b) (4)	16 Dec 2020 19:35:17
User opened query 'Unable to locate this end date in EMR, kindly provide source. ' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 15:49:06
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 20:29:27
User entered '30 Sep 2020' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 20:29:27
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:17:47
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User entered empty.	System	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:17:57
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:17:59
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:03
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:05
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:06
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:08
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:10
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:12
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:14
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:18
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:22
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:25
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:33
User entered 'Not Related (NOT RELATED)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:35
User entered 'Not Related (NOT RELATED)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:15:15
User closed query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 01 Sept 2020 and AE#1 has a start date 16 Sept 2020. Per pages 42-43 of CCGs version 3.0, 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)	24 Dec 2020 07:35:05
Query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 01 Sept 2020 and AE#1 has a start date 16 Sept 2020. Per pages 42-43 of CCGs version 3.0, 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).	Krishna Shah (b) (4) (b) (4)	23 Dec 2020 16:16:52
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	23 Dec 2020 16:16:44
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	23 Dec 2020 16:16:44
User opened query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 01 Sept 2020 and AE#1 has a start date 16 Sept 2020. Per pages 42-43 of CCGs version 3.0, 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)	23 Dec 2020 09:14:01
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:18:41
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 15:17:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 15:17:05
User entered 'None (NONE)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:17:05
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 15:15:56
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:46
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:50
User entered 'I'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:52
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 22:11:57
DataPoint Un-verified.	Krishna Shah (b) (4)	15 Dec 2020 20:29:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Krishna Shah (b) (4) (b) (4)	15 Dec 2020 20:29:27
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:18:54
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 15:17:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 15:17:05
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:17:05
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 15:15:56
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

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 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:18:57
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:00
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User entered '0'	System	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37
User entered '0'	System	28 Sep 2020 15:15:56

US3822003

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:37

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:10
User coded data point as SOC: Gastrointestinal disorders, HLT: Salivary gland conditions, HLT: Oral dryness and saliva altered, PT: Salivary hypersecretion, LLT: Saliva secretion excessive - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 07:05:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 07:05:35
Data point term sent to Coder	System	19 Oct 2020 18:05:32
User entered 'excessive saliva on side nasal swab collected'	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:25
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:27
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:33
User entered '4 Aug 2020'	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:35
User entered '11:30'	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User entered '4 Aug 2020 11:30'	System	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:38
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:42
User entered '4 Aug 2020'	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:44
User entered '11:50'	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User entered '4 Aug 2020 11:50'	System	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:49
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:52
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:57
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:59
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:01
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:03
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:05
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:06
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:08
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:12
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:14
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:16
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:24
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:26
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:28
User entered 'None (NONE)'	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:32
User entered 'l'	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:34
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:37
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[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 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:41
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:54
User entered 'Pt with saliva in posterior pharynx, on side of nasal swab. No difficulty swallowing, no shortness of breath, no wheezing. No swelling on exam.'	(b) (4), (b) (6)	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User entered '0'	System	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43
User entered 'I'	System	19 Oct 2020 18:04:55

US3822003

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:00:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:43

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 17:22:51
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:19:56
User entered	System	29 Oct 2020 13:19:51
'USA-US126-2020-mRNA-1273-P301000007'		
User entered 'New'	(b) (4), (b) (6)	29 Oct 2020 13:19:51

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:23:11
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:50:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:50:41
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:50:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:50:40
Data point term sent to Coder	System	29 Oct 2020 14:01:11
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	System	29 Oct 2020 14:00:16
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' answered with 'updated ' (Site from System).	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:00:16
Data point term sent to Coder	System	29 Oct 2020 14:00:09
User entered 'MYOCARDIAL INFARCTION' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:00:09
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	Coder Import (b) (4) (b) (4)	29 Oct 2020 00:59:27
Data point term sent to Coder	System	28 Oct 2020 15:37:04
User entered 'Coronary artery disease, myocardial infarction'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:24:30
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:24:32
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:24:35
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:24:41
User entered '24 Oct 2020'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:24:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:24:45
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:24:47
User entered '27 Oct 2020'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:24:52
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:24:54
User entered 'Grade 3/Severe (Grade 3/Severe)'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:24:58
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

Death

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:05
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:25:07
User entered '0'	Krishna Shah (b) (4)	28 Oct 2020 15:36:38
	(b) (4)	

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:10
User entered 'I'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:12
User entered '24 Oct 2020'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:14
User entered '27 Oct 2020'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:19
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:21
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:23
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:25
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:25:29
User entered '0'	Krishna Shah (b) (4)	28 Oct 2020 15:36:38
	(b) (4)	

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:31
User entered 'Not Related (NOT RELATED)'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:35
User entered 'Not Related (NOT RELATED)'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:38
User entered 'Not Applicable (NOT APPLICABLE)'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

None

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:25:40
User entered '0'	Krishna Shah (b) (4)	28 Oct 2020 15:36:38
	(b) (4)	

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:45:14
User closed query 'Per DM CLR: Please review Other Action Taken and please note, there is a recorded ConMed that match this AE. However, ConMed is not selected as Other Action Taken. Please review Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 12:35:24
Query 'Per DM CLR: Please review Other Action Taken and please note, there is a recorded ConMed that match this AE. However, ConMed is not selected as Other Action Taken. Please review Other Action Taken as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 14:38:28
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 14:38:22
User entered '1' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 14:38:22
User opened query 'Per DM CLR: Please review Other Action Taken and please note, there is a recorded ConMed that match this AE. However, ConMed is not selected as Other Action Taken. Please review Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 00:01:03
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:45
User entered 'I'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

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 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:55
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
User closed query 'Per CDM: Site response noted; however both EKG and Hearth Cath HAVE NOT been recorded in the Concomitant Procedure form. Per CCGs v4.0 page 50, "If reason for the procedure or surgery is due to an adverse event, the date of the procedure must correspond to the adverse event start/stop dates." Please review and update the ConProc eCRF correctly. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 09:08:18
Query 'Per CDM: Site response noted; however both EKG and Hearth Cath HAVE NOT been recorded in the Concomitant Procedure form. Per CCGs v4.0 page 50, "If reason for the procedure or surgery is due to an adverse event, the date of the procedure must correspond to the adverse event start/stop dates." Please review and update the ConProc eCRF correctly. Thank you.' answered with 'EKG and Heart Cath have been added to Con Procedures.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 19:31:41
User closed query 'Per DM CLR: SAE Narrative = HAD A LEFT HEART CATH. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 09:23:00
User closed query 'Per DM CLR: SAE Narrative = HE WAS FOUND TO HAVE AN ABNORMAL EKG AND ELEVATED TROPONIN. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 09:22:58
User opened query 'Per CDM: Site response noted; however both EKG and Hearth Cath HAVE NOT been recorded in the Concomitant Procedure form. Per CCGs v4.0 page 50, "If reason for the procedure or surgery is due to an adverse event, the date of the procedure must correspond to the adverse event start/stop dates." Please review and update the ConProc eCRF correctly. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 09:22:52

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = HAD A LEFT HEART CATH. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Already added to con-procedures' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 15:10:59
Query 'Per DM CLR: SAE Narrative = HE WAS FOUND TO HAVE AN ABNORMAL EKG AND ELEVATED TROPONIN. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Already added to con-procedures' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 15:10:52
User opened query 'Per DM CLR: SAE Narrative = HAD A LEFT HEART CATH. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 01:31:43
User opened query 'Per DM CLR: SAE Narrative = HE WAS FOUND TO HAVE AN ABNORMAL EKG AND ELEVATED TROPONIN. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 01:31:36
User closed query 'PV Query: Please provide hospital discharge summary or cardiology note with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342. ' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 15:46:10
User closed query 'PV Query: Please provide the results of troponin labs (including units and reference ranges) and EKG results as reported initially without details.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 15:46:05
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)	19 Nov 2020 15:46:01

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide results of any relevant laboratory tests and diagnostic studies done to evaluate the event (ie. cardiac enzymes, ECG, echocardiogram, x-ray, BNP, etc.). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 15:45:57
Query 'PV Query: Please provide hospital discharge summary or cardiology note with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342. ' answered with 'Records have been provided ' (Site from Safety).	Christina Kennelly (b) (4)	18 Nov 2020 14:14:56
Query 'PV Query: Please provide the results of troponin labs (including units and reference ranges) and EKG results as reported initially without details.' answered with 'troponin values provided above' (Site from Safety).	Christina Kennelly (b) (4)	18 Nov 2020 14:13:41
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 COVID testing was done' (Site from Safety).	Christina Kennelly (b) (4)	18 Nov 2020 14:13:19
Query 'PV Query: Please provide results of any relevant laboratory tests and diagnostic studies done to evaluate the event (ie. cardiac enzymes, ECG, echocardiogram, x-ray, BNP, etc.). Please include units and reference ranges if applicable.' answered with 'ECG: sinus rhythm, T wave inversion in lead 3 Chest xray clear Troponin 0.091, then 11.663 and then 27.973, then 22.049(normal 0.0-0.040	Christina Kennelly (b) (4)	18 Nov 2020 14:13:11
No BNP was done		
Left heart cath with obstructive stenosis of distal OM, elevated LVEDP. Ramus with 60-70% stenosis		
Echo with normal LVEF 55%, normal function. Mild MR. Aortic sclerosis' (Site from Safety).		
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:26:01

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please report if there were any factors that precipitated the event.' canceled (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 23:27:04
User opened query 'PV Query: Please provide hospital discharge summary or cardiology note with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342. ' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 23:25:36
Query 'PV Query: Please provide results of cardiology consult notes or discharge summary when available or applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 23:25:24
Query 'PV Query: PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 23:23:34
Query 'PV Query: Please describe the clinical course of the event, including signs and symptoms.' canceled (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 23:23:20
User closed query 'PV Query: Please provide the date of cardiac catheterization and stent placement there were reported.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 11:26:15
User closed query 'PV Query: Please indicate any risk factors the subject had for the development of the event (hypertension, dyslipidemia, coronary artery disease, previous myocardial infarction, diabetes, cardiomyopathy, valvular heart disease, atrial fibrillation/dysrhythmia, prior CHF, smoking, alcohol, etc). Please provide any relevant medical history including history of similar episodes with onset date(s), severity, treatment and relevant details.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 11:26:12
Query 'PV Query: Please provide the date of cardiac catheterization and stent placement there were reported.' answered with 'Stent was placed on 25Oct20, see conmed procedures. ' (Site from Safety).	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 20:26:09

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please indicate any risk factors the subject had for the development of the event (hypertension, dyslipidemia, coronary artery disease, previous myocardial infarction, diabetes, cardiomyopathy, valvular heart disease, atrial fibrillation/dysrhythmia, prior CHF, smoking, alcohol, etc). Please provide any relevant medical history including history of similar episodes with onset date(s), severity, treatment and relevant details.'	Krishna Shah (b) (4)	06 Nov 2020 20:15:06
answered with 'The patient had hypocholesteremia and Type II diabetes as listed in the medical history. ' (Site from Safety).	(b) (4)	
User opened query 'PV Query: Please provide the date of cardiac catheterization and stent placement there were reported.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 12:59:03
User opened query 'PV Query: Please provide the results of troponin labs (including units and reference ranges) and EKG results as reported initially without details.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 12:58:56
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 12:58:49
User opened query 'PV Query: PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 12:58:22
User opened query 'PV Query: Please report if there were any factors that precipitated the event.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 12:58:11
User opened query 'PV Query: Please provide results of any relevant laboratory tests and diagnostic studies done to evaluate the event (ie. cardiac enzymes, ECG, echocardiogram, x-ray, BNP, etc.). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 12:58:04

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please describe the clinical course of the event, including signs and symptoms.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 12:57:58
User opened query 'PV Query: Please provide results of cardiology consult notes or discharge summary when available or applicable.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 12:57:52
User opened query 'PV Query: Please indicate any risk factors the subject had for the development of the event (hypertension, dyslipidemia, coronary artery disease, previous myocardial infarction, diabetes, cardiomyopathy, valvular heart disease, atrial fibrillation/dysrhythmia, prior CHF, smoking, alcohol, etc). Please provide any relevant medical history including history of similar episodes with onset date(s), severity, treatment and relevant details.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 12:57:42
User entered 'Patient presented to an New Hanover ER 10/24/2020 with chest pain. He was found to have an abnormal EKG and elevated troponin. He was monitored over night and had a left heart cath. He had a stent placed.'	Krishna Shah (b) (4)	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:00:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Oct 2020 15:36:38

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:45:34
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 17:30:12
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:28:13
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 03:50:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 03:50:40
Data point term sent to Coder	System	29 Oct 2020 14:00:09
User entered 'CORONARY ARTERY DISEASE'	Krishna Shah (b) (4)	29 Oct 2020 13:59:50
	(b) (4)	

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:28:16
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 13:59:50

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:28:19
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 13:59:50

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:28:21
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 13:59:50

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:28:25
User entered '24 Oct 2020'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 13:59:50

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:28:28
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 13:59:50

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 13:59:50

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:28:31
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 13:59:50

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:28:33
User entered empty.	Krishna Shah (b) (4)	29 Oct 2020 13:59:50
	(b) (4)	

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:28:35
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 13:59:50

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 13:59:50

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:28:48
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 13:59:50

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:29:01
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 13:59:50

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:29:04
User entered '0'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 13:59:50

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:29:06
User entered '0'	Krishna Shah (b) (4)	29 Oct 2020 13:59:50
	(b) (4)	

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:29:07
User entered '0'	Krishna Shah (b) (4)	29 Oct 2020 13:59:50
	(b) (4)	

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:29:10
User entered empty.	Krishna Shah (b) (4)	29 Oct 2020 13:59:50
	(b) (4)	

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:29:15
User entered empty.	Krishna Shah (b) (4)	29 Oct 2020 13:59:50
	(b) (4)	

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:29:17
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 13:59:50

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:29:23
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 13:59:50

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:29:38
User entered '0'	Krishna Shah (b) (4)	29 Oct 2020 13:59:50
	(b) (4)	

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:29:41
User entered '0'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 13:59:50

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:29:43
User entered '0'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 13:59:50

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:29:46
User entered 'Not Related (NOT RELATED)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 13:59:50

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:29:48
User entered 'Not Related (NOT RELATED)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 13:59:50

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:29:50
User entered 'Not Applicable (NOT APPLICABLE)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 13:59:50

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

None

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:29:54
User entered '0'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 13:59:50

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that is indicated for this AE. Please reconcile with ConMed eCRF and update Indication of the corresponding medications given for this AE as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that is indicated for this AE. Please reconcile with ConMed eCRF and update Indication of the corresponding medications given for this AE as appropriate. Otherwise, clarify.' answered with 'updated conmeds' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 12:35:35
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that is indicated for this AE. Please reconcile with ConMed eCRF and update Indication of the corresponding medications given for this AE as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 14:42:26
User entered '1'	(b) (4), (b) (6)	03 Dec 2020 00:00:49
	(b) (4), (b) (6)	17 Nov 2020 17:29:56
	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 13:59:50

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:38:34
User entered '0'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 13:59:50

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:30:01
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 13:59:50

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[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 18:44:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:30:06
User entered empty.	Krishna Shah (b) (4)	29 Oct 2020 13:59:50
	(b) (4)	

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:30:08
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 13:59:50

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Oct 2020 13:59:50

US3822003

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:00:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Oct 2020 13:59:50

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:51:16
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 12:35:55
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pressure is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 12:35:51
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Angina pectoris, LLT: Chest pain - cardiac - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Dec 2020 17:17:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Dec 2020 17:17:58
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' answered with 'patient was not assessed for COVID. ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 14:43:14
Data point term sent to Coder	System	15 Dec 2020 14:43:08
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pressure is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'updated ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 14:43:03
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 14:42:57
Coding entries removed.	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 14:42:57

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

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[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Cardiac CHEST PRESSURE' reason for change: Data Entry Error	Krishna Shah (b) (4)	15 Dec 2020 14:42:57
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 16:37:19
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pressure is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 03:49:31
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:26:50
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest discomfort, LLT: Chest pressure - version MedDRA\23.0.	Coder Import (b) (4)	16 Nov 2020 21:17:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Nov 2020 21:17:47
	(b) (4)	
Data point term sent to Coder	System	16 Nov 2020 21:17:25
User entered 'Chest pressure'	Kelly Woodell (b) (4)	16 Nov 2020 21:16:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:26:52
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:26:55
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:26:57
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:27:02
User entered '10 Nov 2020'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:45:34
Query 'Per CRIO source, start time is noted as 11:30. Please reconcile and update if applicable.' canceled (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 04:26:07
User opened query 'Per CRIO source, start time is noted as 11:30. Please reconcile and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:27:38
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 18:27:17
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:27:10
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User entered empty.	System	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:27:49
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:27:52
User entered '12 Nov 2020'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:40:29
Query 'Per CRIO source, end time is noted as 10:30. Please reconcile and update if applicable.' canceled (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 04:26:10
User opened query 'Per CRIO source, end time is noted as 10:30. Please reconcile and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:28:55
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User entered empty.	System	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:29:14
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:29:23
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:29:29
User entered '0'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:29:32
User entered '0'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:29:35
User entered '0'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:29:37
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:29:40
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:29:42
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:29:44
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:29:46
User entered '0'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:29:48
User entered '0'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:29:51
User entered '0'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:29:59
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 21:37:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 21:37:34
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:37:34
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 21:16:34
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:40:49
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 15:08:44
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'updated per MD assessment.' (Site from DM).	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 14:56:29
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 14:56:18
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 14:56:18
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 07:58:12
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:30:02
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 21:37:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 21:37:34
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:37:34
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 21:16:34
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:30:04
User entered 'Not Applicable (NOT APPLICABLE)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:30:06
User entered 'I'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:30:10
User entered '0'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:30:24
User entered '0'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:30:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

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 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:30:28
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:30:32
User entered 'The patient started having chest pressure on 11/10/2020. On 11/12/2020 it was still ongoing so the patient presented to the ER. He was diagnosed with Acute Pericarditis.'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User entered '0'	System	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48
User entered '0'	System	16 Nov 2020 21:16:34

US3822003

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:00:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:07:48

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4)	19 Nov 2020 18:41:06
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 15:06:22
User entered	System	17 Nov 2020 19:56:59
'USA-US126-2020-mRNA-1273-P301000008'		
User entered 'New'	(b) (4), (b) (6)	17 Nov 2020 19:56:59

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:31:00
User coded data point as SOC: Cardiac disorders, HLGT: Pericardial disorders, HLT: Noninfectious pericarditis, PT: Pericarditis, LLT: Acute pericarditis - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 21:21:01
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 21:21:01
	(b) (4)	
Data point term sent to Coder	System	16 Nov 2020 21:19:29
User entered 'Acute pericarditis'	Kelly Woodell (b) (4)	16 Nov 2020 21:19:21
	(b) (4)	

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:31:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:19:21

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:31:06
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:19:21

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:31:08
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:19:21

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:31:12
User entered '12 Nov 2020'	Kelly Woodell (b) (4)	16 Nov 2020 21:19:21
	(b) (4)	

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:41:11
Query 'Per CRIO source, start time is noted as 10:30. Please reconcile and update if applicable.' canceled (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 04:26:23
User opened query 'Per CRIO source, start time is noted as 10:30. Please reconcile and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:31:33
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:19:21

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 21:19:21

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 22:14:52
DataPoint Un-verified.	Krishna Shah (b) (4)	15 Dec 2020 14:44:49
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Krishna Shah (b) (4)	15 Dec 2020 14:44:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:31:37
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	16 Nov 2020 21:19:21
	(b) (4)	

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 22:14:54
User closed query 'Unable to locate this data point in source, kindly provide. ' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 22:14:46
Query 'Unable to locate this data point in source, kindly provide. ' answered with 'Please see progress note under subject level in CRIO. ' (Site from CRA).	Krishna Shah (b) (4)	16 Dec 2020 19:36:47
	(b) (4)	
User opened query 'Unable to locate this data point in source, kindly provide. ' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 15:53:55
User closed query 'PV Query: Please provide the event end date.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 19:58:50
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	15 Dec 2020 14:45:14
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	15 Dec 2020 14:45:14
Query 'PV Query: Please provide the event end date.' answered with 'updated ' (Site from Safety).	Krishna Shah (b) (4)	15 Dec 2020 14:44:59
	(b) (4)	
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	15 Dec 2020 14:44:49
DataPoint Un-verified.	Krishna Shah (b) (4)	15 Dec 2020 14:44:49
	(b) (4)	
User entered '13 Nov 2020' reason for change: Data Entry Error	Krishna Shah (b) (4)	15 Dec 2020 14:44:49
	(b) (4)	
User opened query 'PV Query: Please provide the event end date.' (Site from Safety).	(b) (4), (b) (6)	26 Nov 2020 00:15:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:31:39
	(b) (4)	
User entered empty.	Kelly Woodell (b) (4)	16 Nov 2020 21:19:21
	(b) (4)	

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:31:42
User entered empty.	Kelly Woodell (b) (4)	16 Nov 2020 21:19:21
	(b) (4)	

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 21:19:21

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

Severity

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 22:14:55
User closed query 'PV Query: As the event resulted in hospitalization, please consider upgrading intensity to grade 4. If not, please further clarify.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 19:58:55
Query 'PV Query: As the event resulted in hospitalization, please consider upgrading intensity to grade 4. If not, please further clarify.' answered with 'updated' (Site from Safety).	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 14:46:17
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 14:45:33
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 14:45:33
User opened query 'PV Query: As the event resulted in hospitalization, please consider upgrading intensity to grade 4. If not, please further clarify.' (Site from Safety).	(b) (4), (b) (6)	26 Nov 2020 00:15:46
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:31:46
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:19:21

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
User closed query 'Please confirm if this is a second SAE for this subject and needs to be submitted as such.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:29:31
Query 'Please confirm if this is a second SAE for this subject and needs to be submitted as such.' answered with 'This SAE is the 2nd and has been submitted as such' (Site from CRA).	Kelly Woodell (b) (4) (b) (4)	18 Nov 2020 13:23:06
User opened query 'Please confirm if this is a second SAE for this subject and needs to be submitted as such.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:36:51
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:31:49
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:19:21

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:32:04
User entered '0'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:19:21

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:32:08
User entered '0'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:19:21

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:32:11
User entered 'I'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:19:21

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 14:30:41
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 18:32:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:32:15
User entered '12 Nov 2020'	Kelly Woodell (b) (4)	16 Nov 2020 21:19:21
	(b) (4)	

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 14:30:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 18:32:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:32:23
	(b) (4)	
User entered '13 Nov 2020'	Kelly Woodell (b) (4)	16 Nov 2020 21:19:21
	(b) (4)	

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:32:42
User entered 'No (N)'	Kelly Woodell (b) (4)	16 Nov 2020 21:19:21
	(b) (4)	

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:32:45
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:19:21

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:33:03
User entered '0'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:19:21

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:33:05
User entered '0'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:19:21

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:33:15
User entered '0'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:19:21

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 15:09:11
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 15:06:11
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 14:30:48
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 14:24:36
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 14:24:34
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'completed' (Site from Safety).	Kelly Woodell (b) (4)	18 Nov 2020 13:25:53
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kelly Woodell (b) (4)	18 Nov 2020 13:23:24
	(b) (4)	
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 21:11:11
Query 'Data is required. Please complete.' answered with 'Will be added when assessed.' (Site from System).	Kelly Woodell (b) (4)	16 Nov 2020 21:19:47
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 21:19:21
User entered empty.	Kelly Woodell (b) (4)	16 Nov 2020 21:19:21
	(b) (4)	

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:33:19
User entered 'Not Related (NOT RELATED)'	Kelly Woodell (b) (4)	16 Nov 2020 21:37:56
reason for change: Data Entry Error	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Kelly Woodell (b) (4)	16 Nov 2020 21:19:21
	(b) (4)	

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:33:23
User entered 'Not Applicable (NOT APPLICABLE)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:19:21

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:33:27
User entered '0'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:19:21

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:33:29
User entered 'I'	Kelly Woodell (b) (4)	16 Nov 2020 21:19:21
	(b) (4)	

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:33:31
User entered '0'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:19:21

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 22:14:59
	(b) (4), (b) (6)	15 Dec 2020 19:59:08
User closed query 'PV Query: Please provide the final event outcome, when available.' (Site from Safety).		
Query 'PV Query: Please provide the final event outcome, when available.' answered with 'updated' (Site from Safety).	Krishna Shah (b) (4)	15 Dec 2020 14:46:36
	(b) (4)	
DataPoint Un-verified.	Krishna Shah (b) (4)	15 Dec 2020 14:45:14
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Krishna Shah (b) (4)	15 Dec 2020 14:45:14
Data Entry Error	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available.' (Site from Safety).	(b) (4), (b) (6)	26 Nov 2020 00:14:57
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:33:33
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Kelly Woodell (b) (4)	16 Nov 2020 21:19:21
	(b) (4)	

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[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 18:44:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:33:36
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:19:21

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:44:30
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) (4), (b) (6)	15 Dec 2020 19:59:16
User closed query 'PV Query: The subject was prescribed colchicine for pericarditis. Was the pericarditis assessed as being due to increased uremia?' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 19:59:13
Query 'PV Query: The subject was prescribed colchicine for pericarditis. Was the pericarditis assessed as being due to increased uremia?' answered with 'pericarditis was due to MI' (Site from Safety).	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 14:44:15
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 'Patient not tested for COVID' (Site from Safety).	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 14:43:51
User opened query 'PV Query: The subject was prescribed colchicine for pericarditis. Was the pericarditis assessed as being due to increased uremia?' (Site from Safety).	(b) (4), (b) (6)	26 Nov 2020 00:15:27
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)	26 Nov 2020 00:14:51
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:33:38
User entered 'The patient presented to the ER with chest pressure and was admitted. He was diagnosed with acute pericarditis. An EKG was completed and showed incomplete right bundle branch block, left anterior fascicular block. It was worse in the supine position. Chest x-ray showed no acute abnormality.'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:19:21

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Nov 2020 21:19:21

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Nov 2020 21:19:21

US3822003

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:00:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Nov 2020 21:19:21

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:00:59

[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 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:33:58
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:20:01

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 22:22:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 22:22:49
Data point term sent to Coder	System	16 Sep 2020 22:22:07
User entered 'Tylenol'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:21:33

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:21:33

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN, HEADACHE, SWELLING AT INJECTION SITE, CHILLS, FATIGUE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN, HEADACHE, SWELLING AT INJECTION SITE, CHILLS, FATIGUE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 07:36:20
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN, HEADACHE, SWELLING AT INJECTION SITE, CHILLS, FATIGUE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN, HEADACHE, SWELLING AT INJECTION SITE, CHILLS, FATIGUE did not meet the AE reporting criteria.' answered with 'The solicited AEs did not meet AE reporting criteria. Medication was added per query on daily dose CRF. ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:22:01

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:59

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN, HEADACHE, SWELLING AT INJECTION SITE, CHILLS, FATIGUE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN, HEADACHE, SWELLING AT INJECTION SITE, CHILLS, FATIGUE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 04:32:29
User entered 'Injection site pain, headache, swelling at injection site, chills, fatigue'	Kelly Woodell (b) (4)	16 Sep 2020 22:21:33

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '500'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:21:33

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'mg (mg)'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:21:33

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:21:33

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'as needed (PRN)'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:21:33

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:21:33

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Oral (ORAL)'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:21:33

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:21:33

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '01 Sep 2020'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:21:33

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '0'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:21:33

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:21:33

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '02 Sep 2020'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:21:33

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:21:33

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:19
User entered empty.	System	16 Sep 2020 22:21:33

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:19
User entered empty.	System	16 Sep 2020 22:21:33

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:19
User entered empty.	System	16 Sep 2020 22:21:33

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:49:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 22:23:52
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 22:23:52
	(b) (4)	
Data point term sent to Coder	System	16 Sep 2020 22:23:08
User entered 'simvastatin'	Kelly Woodell (b) (4)	16 Sep 2020 22:22:43
	(b) (4)	

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:22:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'hypercholesterolemia'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:22:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '20'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:22:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'mg (mg)'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:22:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:22:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'once daily (QD)'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:22:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:22:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Oral (ORAL)'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:22:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:22:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '03 Dec 2018'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:22:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '0'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:22:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:22:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:22:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:22:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 22:22:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 22:22:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 22:22:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:49:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 22:24:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	16 Sep 2020 22:24:09
User entered 'metformin'	Kelly Woodell (b) (4)	16 Sep 2020 22:23:43
	(b) (4)	

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:23:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'diabetes mellitus II'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:23:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '500'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:23:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'mg (mg)'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:23:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:23:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'once daily (QD)'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:23:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:23:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Oral (ORAL)'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:23:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:23:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '28 Jan 2020'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:23:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '0'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:23:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:23:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:23:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:23:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 22:23:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 22:23:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 22:23:43

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:35
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE, PRODUCTSYNONYM: MEDROL DOSEPAK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:33:27
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 07:33:27
User signature succeeded.	Christina Kennelly (b) (4) (b) (4)	02 Apr 2021 19:58:40
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE, PRODUCTSYNONYM: MEDROL [METHYLPREDNISOLONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 08:03:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 08:03:15
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:49:40
Data point term sent to Coder	System	04 Nov 2020 16:55:29
Coding entries removed.	Kelly Woodell (b) (4) (b) (4)	04 Nov 2020 16:54:37

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:59

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: METHYLPREDNISOLONE, PRODUCTSYNONYM: MEDROL DOSEPAK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 11:32:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 11:32:52
Data point term sent to Coder	System	28 Sep 2020 15:15:03
User entered 'Medrol pack'	Krishna Shah (b) (4)	28 Sep 2020 15:14:38

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:14:38

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User closed query 'Per DM CLR: Please specify the location and/or type of GROWING RASH. 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 Nov 2020 04:23:25
Query 'Per DM CLR: Please specify the location and/or type of GROWING RASH. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match' answered with 'updated' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	04 Nov 2020 16:54:43
User entered 'Urticarial rash (right arm)' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	04 Nov 2020 16:54:37
User opened query 'Per DM CLR: Please specify the location and/or type of GROWING RASH. 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)	23 Oct 2020 04:34:31
User entered 'Growing rash'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:14:38

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '4'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:14:38

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'mg (mg)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:14:38

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:14:38

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'once daily (QD)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:14:38

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:14:38

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Oral (ORAL)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:14:38

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:14:38

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '16 Sep 2020'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:14:38

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:14:38

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:41:08
User closed query 'Per CRIO. Medrol Pack stop date is 22SEP2020. Please reconcile and update EDC if applicable.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 15:41:04
Query 'Per CRIO. Medrol Pack stop date is 22SEP2020. Please reconcile and update EDC if applicable.' answered with 'updated' (Site from CRA).	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 14:57:27
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 14:57:20
User entered 'No (N)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 14:57:20
User opened query 'Per CRIO. Medrol Pack stop date is 22SEP2020. Please reconcile and update EDC if applicable.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 19:26:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:14:38

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:41:10
DataPoint Un-verified.	Krishna Shah (b) (4)	18 Nov 2020 14:57:20
User entered '22 Sep 2020' reason for change: Data Entry Error	(b) (4) Krishna Shah (b) (4)	18 Nov 2020 14:57:20
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:14:38

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:14:38

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:35
User entered '1'	System	28 Sep 2020 15:14:38

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:35
User entered '1'	System	28 Sep 2020 15:14:38

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:35
User entered '804 (804)'	System	28 Sep 2020 15:14:38

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PERTUSSIS VACCINES, PRODUCT: DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID, PRODUCTSYNONYM: TDAP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:51:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:51:09
Data point term sent to Coder	System	29 Oct 2020 14:06:20
User entered 'TDAP vaccine'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:05:37

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User closed query 'Per CRIO source, Prophylaxis is noted as "No". Please reconcile and update as applicable.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:42:42
Query 'Per CRIO source, Prophylaxis is noted as "No". Please reconcile and update as applicable.' answered with 'CRIO updated ' (Site from CRA).	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 14:58:47
User opened query 'Per CRIO source, Prophylaxis is noted as "No". Please reconcile and update as applicable.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 19:15:57
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:05:37

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'vaccine'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:05:37

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'unk'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:05:37

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'mL (mL)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:05:37

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:05:37

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'once (ONCE)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:05:37

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:05:37

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Intramuscular (INTRAMUSCULAR)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:05:37

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:05:37

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '12 Apr 2016'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:05:37

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '0'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:05:37

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:05:37

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '12 Apr 2016'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:05:37

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:05:37

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:41
User entered empty.	System	29 Oct 2020 14:05:37

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:41
User entered empty.	System	29 Oct 2020 14:05:37

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:41
User entered empty.	System	29 Oct 2020 14:05:37

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:49
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 06:02:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 06:02:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
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 21:23:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 21:23:07
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)	30 Oct 2020 03:51:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:51:12
Data point term sent to Coder	System	29 Oct 2020 14:07:24
User entered 'Influenza'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:06:25

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:06:25

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'vaccine'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:06:25

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'unk'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:06:25

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'mL (mL)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:06:25

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:06:25

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'once (ONCE)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:06:25

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:06:25

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Intramuscular (INTRAMUSCULAR)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:06:25

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:06:25

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '16 Oct 2019'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:06:25

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '0'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:06:25

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:06:25

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '16 Oct 2019'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:06:25

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:06:25

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:49
User entered empty.	System	29 Oct 2020 14:06:25

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:49
User entered empty.	System	29 Oct 2020 14:06:25

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:49
User entered empty.	System	29 Oct 2020 14:06:25

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:52
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 06:02:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 06:02:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
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 21:23:08
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 21:23:08
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)	30 Oct 2020 03:51:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:51:13
Data point term sent to Coder	System	29 Oct 2020 14:07:25
User entered 'Influenza'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:07:16

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:52
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:07:16

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:52
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'vaccine'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:07:16

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:52
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'unk'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:07:16

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:52
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'mL (mL)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:07:16

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:52
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:07:16

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:52
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'once (ONCE)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:07:16

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:52
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:07:16

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:52
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Intramuscular (INTRAMUSCULAR)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:07:16

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:52
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:07:16

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:52
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '1 Oct 2018'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:07:16

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:52
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '0'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:07:16

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:52
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:07:16

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:52
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '1 Oct 2018'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:07:16

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:52
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:07:16

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:52
User entered empty.	System	29 Oct 2020 14:07:16

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:52
User entered empty.	System	29 Oct 2020 14:07:16

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:33:52
User entered empty.	System	29 Oct 2020 14:07:16

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:51:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:51:46
Data point term sent to Coder	System	29 Oct 2020 14:09:32
User entered 'Pneumococcal'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:08:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:08:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'vaccine'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:08:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'unk'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:08:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'mL (mL)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:08:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:08:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'once (ONCE)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:08:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:08:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Intramuscular (INTRAMUSCULAR)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:08:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:08:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '10 Sep 2016'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:08:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '0'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:08:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:08:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '10 Sep 2016'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:08:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:11
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:08:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:11
User entered empty.	System	29 Oct 2020 14:08:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:11
User entered empty.	System	29 Oct 2020 14:08:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:11
User entered empty.	System	29 Oct 2020 14:08:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:15
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
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)	30 Oct 2020 03:51:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:51:44
Data point term sent to Coder	System	29 Oct 2020 14:09:45
User entered 'Zoster recombinant'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:09:28

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:15
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:09:28

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:15
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'vaccine'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:09:28

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:15
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'unk'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:09:28

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:15
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'mL (mL)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:09:28

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:15
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:09:28

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:15
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'once (ONCE)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:09:28

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:15
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:09:28

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:15
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Intramuscular (INTRAMUSCULAR)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:09:28

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:15
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:09:28

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:15
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '3 Mar 2020'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:09:28

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:15
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '0'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:09:28

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:15
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:09:28

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:15
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '3 Mar 2020'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:09:28

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:15
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:09:28

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:15
User entered empty.	System	29 Oct 2020 14:09:28

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:15
User entered empty.	System	29 Oct 2020 14:09:28

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:15
User entered empty.	System	29 Oct 2020 14:09:28

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
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)	30 Oct 2020 03:51:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:51:57
Data point term sent to Coder	System	29 Oct 2020 14:10:50
User entered 'zoster recombinant'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:10:24

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:10:24

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'vaccine'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:10:24

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'unk'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:10:24

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'mL (mL)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:10:24

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:10:24

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'once (ONCE)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:10:24

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:10:24

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Intramuscular (INTRAMUSCULAR)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:10:24

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:10:24

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '5 Dec 2019'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:10:24

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '0'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:10:24

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:10:24

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '5 Dec 2019'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:10:24

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:10:24

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:19
User entered empty.	System	29 Oct 2020 14:10:24

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:19
User entered empty.	System	29 Oct 2020 14:10:24

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:19
User entered empty.	System	29 Oct 2020 14:10:24

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:59

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Dec 2020 15:58:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 15:58:30
Data point term sent to Coder Coding entries removed.	System Krishna Shah (b) (4)	15 Dec 2020 14:42:06 15 Dec 2020 14:41:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:52:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:52:04
Data point term sent to Coder User entered 'Atorvastatin'	System Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:11:51 29 Oct 2020 14:11:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:11:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:54:59
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 14:41:34
User entered 'MYOCARDIAL INFARCTION, CORONARY ARTERY DISEASE' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 14:41:34
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Myocardial infarction'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:11:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '80'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:11:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'mg (mg)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:11:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:11:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'once daily (QD)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:11:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:11:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Oral (ORAL)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:11:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:11:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '24 Oct 2020'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:11:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '0'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:11:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:11:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:11:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:11:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 14:11:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 14:11:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 14:11:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:49:40
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: PRASUGREL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 03:53:59
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 03:53:59
	(b) (4)	
Data point term sent to Coder	System	29 Oct 2020 14:13:53
User entered 'Prasugrel'	Krishna Shah (b) (4)	29 Oct 2020 14:13:36
	(b) (4)	

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:13:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Myocardial infarction'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:13:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '10'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:13:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'mg (mg)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:13:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:13:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'once daily (QD)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:13:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:13:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Oral (ORAL)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:13:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:13:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '25 Oct 2020'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:13:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '0'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:13:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:13:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:13:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:13:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 14:13:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 14:13:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 14:13:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Dec 2020 15:56:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 15:56:51
Data point term sent to Coder Coding entries removed.	System Krishna Shah (b) (4)	15 Dec 2020 14:42:05 15 Dec 2020 14:41:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:55:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:55:48
Data point term sent to Coder User entered 'aspirin'	System Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:14:55 29 Oct 2020 14:14:22

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:14:22

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User closed query 'Per DM CLR: This Conmed is given for the AE#3. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 12:50:40
Query 'Per DM CLR: This Conmed is given for the AE#3. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' answered with 'Per source aspirin is taken post MI which is AE #3' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 15:13:45
User opened query 'Per DM CLR: This Conmed is given for the AE#3. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 08:31:39
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 15:55:11
DataPoint Un-verified.	Krishna Shah (b) (4)	15 Dec 2020 14:41:50
User entered 'MYOCARDIAL INFARCTION, CORONARY ARTERY DISEASE' reason for change: Data Entry Error	(b) (4) Krishna Shah (b) (4)	15 Dec 2020 14:41:50
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Myocardial infarction'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:14:22

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '81'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:14:22

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'mg (mg)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:14:22

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:14:22

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'once daily (QD)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:14:22

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:14:22

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Oral (ORAL)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:14:22

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:14:22

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '24 Oct 2020'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:14:22

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '0'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:14:22

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:14:22

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:14:22

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:14:22

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 14:14:22

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 14:14:22

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 14:14:22

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:59

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:49:40
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)	30 Oct 2020 03:56:10
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 03:56:10
	(b) (4)	
Data point term sent to Coder User entered 'lisinopril'	System	29 Oct 2020 14:15:56
	Krishna Shah (b) (4)	29 Oct 2020 14:15:27
	(b) (4)	

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:15:27

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'myocardial infarction'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:15:27

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '2.5'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:15:27

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'mg (mg)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:15:27

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:15:27

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'once daily (QD)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:15:27

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:15:27

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Oral (ORAL)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:15:27

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:15:27

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '25 Oct 2020'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:15:27

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '0'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:15:27

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:15:27

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:15:27

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:15:27

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 14:15:27

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 14:15:27

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 14:15:27

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
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) Coders Import (b) (4) (b) (4)	18 Dec 2020 09:52:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	18 Dec 2020 09:52:06
Data point term sent to Coders Coding entries removed.	System Krishna Shah (b) (4)	15 Dec 2020 14:42:06 15 Dec 2020 14:42:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
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.	Coders Import (b) (4) (b) (4)	30 Oct 2020 04:26:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	30 Oct 2020 04:26:55
Data point term sent to Coders User entered 'Metoprolol succinate'	System Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:19:03 29 Oct 2020 14:18:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:18:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:55:20
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 14:42:06
User entered 'MYOCARDIAL INFARCTION, CORONARY ARTERY DISEASE' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	15 Dec 2020 14:42:06
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'myocardial infarction'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:18:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '25'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:18:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'mg (mg)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:18:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:18:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'twice daily (BID)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:18:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:18:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Oral (ORAL)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:18:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:18:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '24 Oct 2020'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:18:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '0'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:18:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:18:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:18:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	29 Oct 2020 14:18:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Oct 2020 14:18:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 14:18:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 14:18:36

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM, PRODUCT: COLCHICINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 02:13:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 02:13:57
Data point term sent to Coder	System	16 Nov 2020 21:21:30
User entered 'Colchicine'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:00

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 12:50:54
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 17:38:18
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:38:07
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 17:38:07
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 08:32:01
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:00

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User closed query 'Please review CRIO as Indication noted is "Myocardial Infarction". Please review and reconcile as applicable.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:06
Query 'Please review CRIO as Indication noted is "Myocardial Infarction". Please review and reconcile as applicable.' answered with 'Please review CRIO, Acute pericarditis list was hospitalized where he received this medication. ' (Site from CRA).	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 15:01:11
User opened query 'Please review CRIO as Indication noted is "Myocardial Infarction". Please review and reconcile as applicable.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 19:40:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Acute Pericarditis'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:00

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '0.6'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:00

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'mg (mg)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:00

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:00

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'once daily (QD)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:00

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:00

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Oral (ORAL)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:00

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:00

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 13:26:47
User entered '12 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Feb 2021 13:26:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '14 Nov 2020'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:00

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '0'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:00

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User closed query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 11:33:05
Query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 13:26:29
DataPoint Un-verified.	(b) (4), (b) (6)	01 Feb 2021 13:26:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Feb 2021 13:26:24
User opened query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Jan 2021 02:36:15
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:00

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User closed query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4)	
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	01 Feb 2021 13:26:47
DataPoint Un-verified.	System	01 Feb 2021 13:26:24
	(b) (4), (b) (6)	01 Feb 2021 13:26:24
User entered '13 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Feb 2021 13:26:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Kelly Woodell (b) (4)	16 Nov 2020 21:21:00
	(b) (4)	

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:00

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:45
User entered '1'	System	16 Nov 2020 21:21:00

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:45
User entered '1'	System	16 Nov 2020 21:21:00

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:45
User entered '804 (804)'	System	16 Nov 2020 21:21:00

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 07:16:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 07:16:54
Data point term sent to Coder	System	16 Nov 2020 21:22:30
User entered 'Ibuprofen'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:45

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 12:51:04
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 17:38:41
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:38:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 17:38:33
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 08:32:17
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:45

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Acute Pericarditis'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:45

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '600'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:45

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'mg (mg)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:45

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:45

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'three times daily (TID)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:45

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:45

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Oral (ORAL)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:45

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:45

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:45:47
User closed query 'Per CRIO source, Start Date is 12NOV2020. Please reconcile and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 15:45:45
Query 'Per CRIO source, Start Date is 12NOV2020. Please reconcile and update if applicable.' answered with 'updated' (Site from CRA).	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 15:01:32
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 15:01:26
User entered '12 Nov 2020' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 15:01:26
User opened query 'Per CRIO source, Start Date is 12NOV2020. Please reconcile and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 19:11:58
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '13 Nov 2020'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:45

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '0'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:45

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 11:33:22
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 13:27:33
DataPoint Un-verified.	(b) (4), (b) (6)	01 Feb 2021 13:27:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Feb 2021 13:27:27
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Jan 2021 02:38:17
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:45

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 13:27:27
User entered '13 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Feb 2021 13:27:27
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:45

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:51
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:21:45

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:51
User entered '3'	System	16 Nov 2020 21:21:45

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:51
User entered '1'	System	16 Nov 2020 21:21:45

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:51
User entered '804 (804)'	System	16 Nov 2020 21:21:45

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 07:20:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 07:20:53
Data point term sent to Coder	System	16 Nov 2020 21:24:32
User entered 'Pantoprazole'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:23:46

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 07:49:29
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.	(b) (4), (b) (6)	24 Feb 2021 13:56:36
' answered with 'updated' (Site from DM).		
DataPoint Un-verified.	(b) (4), (b) (6)	24 Feb 2021 13:56:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 13:56:30
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 22:23:37
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:23:46

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Acute pericarditis'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:23:46

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '40'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:23:46

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'mg (mg)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:23:46

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:23:46

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'once daily (QD)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:23:46

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:23:46

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Oral (ORAL)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:23:46

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:23:46

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 13:28:05
User entered '12 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Feb 2021 13:28:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '14 Nov 2020'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:23:46

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered '0'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:23:46

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 11:33:35
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 13:28:11
DataPoint Un-verified.	(b) (4), (b) (6)	01 Feb 2021 13:28:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Feb 2021 13:28:05
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Jan 2021 02:39:43
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:23:46

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 13:28:05
User entered '13 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Feb 2021 13:28:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:23:46

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:49:40
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:23:46

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:56
User entered '1'	System	16 Nov 2020 21:23:46

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:56
User entered '1'	System	16 Nov 2020 21:23:46

US3822003

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:56
User entered '804 (804)'	System	16 Nov 2020 21:23:46

US3822003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:00:59

[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 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:26:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 16:44:46
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:00:27

US3822003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:00:59

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:27:29
User entered '25 Oct 2020'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 16:45:01

US3822003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:00:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:27:29
User entered 'cardiac stent'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 16:45:01

US3822003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:00:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:27:29
User entered 'Adverse Event (AE)'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 16:45:01

US3822003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:00:59

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:27:29
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 16:45:01

US3822003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:00:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:13
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:27:29
User entered '12 Nov 2020'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:25:58

US3822003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:00:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:13
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:27:29
User entered 'Cardiac lab work'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:25:58

US3822003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:00:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:13
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:27:29
User entered 'Adverse Event (AE)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:25:58

US3822003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:00:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:13
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:27:29
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:25:58

US3822003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:00:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:15
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:27:29
User entered '12 Nov 2020'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:26:38

US3822003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:00:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:15
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:27:29
User entered 'Chest x-ray'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:26:38

US3822003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:00:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:15
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:27:29
User entered 'Adverse Event (AE)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:26:38

US3822003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:00:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:15
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:27:29
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:26:38

US3822003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:00:59

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:27:29
User entered '12 Nov 2020'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:27:40

US3822003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:00:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:27:29
User entered 'Echocardiogram'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:27:40

US3822003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:00:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:27:29
User entered 'Adverse Event (AE)'	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:27:40

US3822003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:00:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:27:29
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Nov 2020 21:27:40

US3822003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:00:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:22
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered '24 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:18:37

US3822003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:00:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:22
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered 'Heart Cath'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:18:37

US3822003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:00:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:22
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:18:37

US3822003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:00:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:22
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:18:37

US3822003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:00:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:26
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered '18 Nov 2020'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:25:48

US3822003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:00:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:26
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered 'Electrocardiogram'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:25:48

US3822003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:00:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:26
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User closed query 'Per CDM: ELECTROCARDIOGRAM- 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 08:40:34
Query 'Per CDM: ELECTROCARDIOGRAM- 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 18:26:28
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 18:26:22
User opened query 'Per CDM: ELECTROCARDIOGRAM- 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 09:57:23
User entered 'Medical History (MH)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 19:26:58
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	26 Jan 2021 19:25:48

US3822003

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:00:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:26
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:25:48

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'USA-US126-2020-MRNA-1273-P301000007'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'Yes (Y)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'No (N)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'No (N)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'Yes (Y)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'No (N)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'No (N)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'No (N)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'Christina'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'Kennelly'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:10:24
	(b) (4), (b) (6)	
User closed query 'Please complete each field for address.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 15:33:10
Query 'Please complete each field for address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:42:26
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:42:20
	(b) (4), (b) (6)	
User entered '6060 PIEDMONT ROW DRIVE SOUTH' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:42:20
User opened query 'Please complete each field for address.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 15:40:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:03:53
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:48:31
	(b) (4), (b) (6)	
User closed query 'Please separate the city, state and zip into independent fields.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:48:29
Query 'Please separate the city, state and zip into independent fields.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 13:27:23
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:17
User opened query 'Please separate the city, state and zip into independent fields.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 13:14:37
User closed query 'Please complete all fields for address.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 13:14:37
Query 'Please complete all fields for address.' answered with 'updated' (Site from CRA).	Krishna Shah (b) (4)	19 Nov 2020 18:13:07
	(b) (4)	
User entered '6060 Piedmont Row Dr S, Charlotte, NC 28210'	Krishna Shah (b) (4)	19 Nov 2020 18:13:01
	(b) (4)	
User opened query 'Please complete all fields for address.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 17:15:27

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:10:25
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:42:20
User entered 'CHARLOTTE' reason for change:	(b) (4), (b) (6)	26 Jan 2021 14:42:20
Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:03:53
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:48:33
User entered 'CHARLOTTE' reason for change:	(b) (4), (b) (6)	23 Nov 2020 13:27:17
Data Entry Error		
User entered empty.	Krishna Shah (b) (4)	19 Nov 2020 18:13:01
	(b) (4)	

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4)	05 Feb 2021 14:10:27
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:42:20
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:42:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:03:53
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:48:36
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:17
User entered empty.	Krishna Shah (b) (4)	19 Nov 2020 18:13:01
	(b) (4)	

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:10:29
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:42:20
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:42:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:03:53
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:48:39
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:17
User entered empty.	Krishna Shah (b) (4)	19 Nov 2020 18:13:01
	(b) (4)	

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 12:13:14
User entered 'US'	System	29 Oct 2020 13:20:22

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Dec 2020 21:04:18
User entered '2'	System	30 Oct 2020 12:13:22
User entered '1'	System	29 Oct 2020 13:20:22

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'USA-US126-2020-MRNA-1273-P301000007'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'Yes (Y)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'No (N)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'No (N)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'Yes (Y)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'No (N)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'No (N)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'No (N)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'Christina'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'Kennelly'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:10:24
	(b) (4), (b) (6)	
User closed query 'Please complete each field for address.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 15:33:10
Query 'Please complete each field for address.'	(b) (4), (b) (6)	26 Jan 2021 14:42:26
answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:42:20
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:42:20
	(b) (4), (b) (6)	26 Jan 2021 14:42:20
User entered '6060 PIEDMONT ROW DRIVE SOUTH' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 15:40:15
User opened query 'Please complete each field for address.' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 21:03:53
Reviewed for Safety.	(b) (4), (b) (6)	
	System	15 Dec 2020 20:00:27
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 20:48:31
DataPoint Verified.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	23 Nov 2020 20:48:29
User closed query 'Please separate the city, state and zip into independent fields.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 13:27:23
Query 'Please separate the city, state and zip into independent fields.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 13:27:17
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Nov 2020 13:14:37
User opened query 'Please separate the city, state and zip into independent fields.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 13:14:37
User closed query 'Please complete all fields for address.' (Site from CRA).	Krishna Shah (b) (4)	19 Nov 2020 18:13:07
Query 'Please complete all fields for address.'	(b) (4)	19 Nov 2020 18:13:01
answered with 'updated' (Site from CRA).	(b) (4)	
User entered '6060 Piedmont Row Dr S, Charlotte, NC 28210'	(b) (4), (b) (6)	17 Nov 2020 17:15:27
User opened query 'Please complete all fields for address.' (Site from CRA).	(b) (4), (b) (6)	

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:10:25
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:42:20
User entered 'CHARLOTTE' reason for change:	(b) (4), (b) (6)	26 Jan 2021 14:42:20
Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:03:53
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:48:33
User entered 'CHARLOTTE' reason for change:	(b) (4), (b) (6)	23 Nov 2020 13:27:17
Data Entry Error		
User entered empty.	Krishna Shah (b) (4)	19 Nov 2020 18:13:01
	(b) (4)	

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4)	05 Feb 2021 14:10:27
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:42:20
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:42:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:03:53
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:48:36
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:17
User entered empty.	Krishna Shah (b) (4)	19 Nov 2020 18:13:01
	(b) (4)	

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4)	05 Feb 2021 14:10:29
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:42:20
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:42:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:03:53
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:48:39
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:17
User entered empty.	Krishna Shah (b) (4)	19 Nov 2020 18:13:01
	(b) (4)	

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 12:13:14
User entered 'US'	System	29 Oct 2020 13:20:22

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Dec 2020 21:04:18
User entered '2'	System	30 Oct 2020 12:13:22
User entered '1'	System	29 Oct 2020 13:20:22

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:00:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
User entered '29/Oct/2020 13:20'	System	29 Oct 2020 13:20:22

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:00:59

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 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 12:13:14
User entered 'I'	(b) (4), (b) (6)	29 Oct 2020 13:20:22

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'USA-US126-2020-MRNA-1273-P301000007'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'Yes (Y)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'No (N)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'No (N)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'Yes (Y)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'No (N)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'No (N)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'No (N)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'Christina'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'Kennelly'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:10:24
	(b) (4), (b) (6)	
User closed query 'Please complete each field for address.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 15:33:10
Query 'Please complete each field for address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:42:26
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:42:20
	(b) (4), (b) (6)	
User entered '6060 PIEDMONT ROW DRIVE SOUTH' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:42:20
User opened query 'Please complete each field for address.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 15:40:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:03:53
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:48:31
	(b) (4), (b) (6)	
User closed query 'Please separate the city, state and zip into independent fields.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:48:29
Query 'Please separate the city, state and zip into independent fields.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 13:27:23
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:17
User opened query 'Please separate the city, state and zip into independent fields.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 13:14:37
User closed query 'Please complete all fields for address.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 13:14:37
Query 'Please complete all fields for address.' answered with 'updated' (Site from CRA).	Krishna Shah (b) (4)	19 Nov 2020 18:13:07
	(b) (4)	
User entered '6060 Piedmont Row Dr S, Charlotte, NC 28210'	Krishna Shah (b) (4)	19 Nov 2020 18:13:01
	(b) (4)	
User opened query 'Please complete all fields for address.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 17:15:27

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:10:25
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:42:20
User entered 'CHARLOTTE' reason for change:	(b) (4), (b) (6)	26 Jan 2021 14:42:20
Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:03:53
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:48:33
User entered 'CHARLOTTE' reason for change:	(b) (4), (b) (6)	23 Nov 2020 13:27:17
Data Entry Error		
User entered empty.	Krishna Shah (b) (4)	19 Nov 2020 18:13:01
	(b) (4)	

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4)	05 Feb 2021 14:10:27
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:42:20
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:42:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:03:53
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:48:36
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:17
User entered empty.	Krishna Shah (b) (4)	19 Nov 2020 18:13:01
	(b) (4)	

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4)	05 Feb 2021 14:10:29
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:42:20
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:42:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:03:53
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:48:39
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:17
User entered empty.	Krishna Shah (b) (4)	19 Nov 2020 18:13:01
	(b) (4)	

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 12:13:14
User entered 'US'	System	29 Oct 2020 13:20:22

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Dec 2020 21:04:18
User entered '2'	System	30 Oct 2020 12:13:22
User entered '1'	System	29 Oct 2020 13:20:22

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:00:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
User entered '30/Oct/2020 08:13'	System	30 Oct 2020 12:13:22

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:00:59

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 19:58:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:03:53
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:14:54
User entered 'I'	(b) (4), (b) (6)	30 Oct 2020 12:13:22

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'USA-US126-2020-MRNA-1273-P301000007'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'Yes (Y)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'No (N)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'No (N)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'Yes (Y)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'No (N)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'No (N)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'No (N)'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'Christina'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:20:13
User entered 'Kennelly'	System	29 Oct 2020 13:19:51

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 14:10:24
	(b) (4), (b) (6)	
User closed query 'Please complete each field for address.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 15:33:10
Query 'Please complete each field for address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:42:26
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:42:20
	(b) (4), (b) (6)	
User entered '6060 PIEDMONT ROW DRIVE SOUTH' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:42:20
User opened query 'Please complete each field for address.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 15:40:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:03:53
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:48:31
	(b) (4), (b) (6)	
User closed query 'Please separate the city, state and zip into independent fields.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:48:29
Query 'Please separate the city, state and zip into independent fields.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 13:27:23
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:17
User opened query 'Please separate the city, state and zip into independent fields.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 13:14:37
User closed query 'Please complete all fields for address.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 13:14:37
Query 'Please complete all fields for address.' answered with 'updated' (Site from CRA).	Krishna Shah (b) (4)	19 Nov 2020 18:13:07
	(b) (4)	
User entered '6060 Piedmont Row Dr S, Charlotte, NC 28210'	Krishna Shah (b) (4)	19 Nov 2020 18:13:01
	(b) (4)	
User opened query 'Please complete all fields for address.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 17:15:27

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4)	05 Feb 2021 14:10:25
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:42:20
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:42:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:03:53
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:48:33
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:17
User entered empty.	Krishna Shah (b) (4)	19 Nov 2020 18:13:01
	(b) (4)	

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4)	05 Feb 2021 14:10:27
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:42:20
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:42:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:03:53
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:48:36
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:17
User entered empty.	Krishna Shah (b) (4)	19 Nov 2020 18:13:01
	(b) (4)	

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4)	05 Feb 2021 14:10:29
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:42:20
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:42:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:03:53
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:48:39
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:17
User entered empty.	Krishna Shah (b) (4)	19 Nov 2020 18:13:01
	(b) (4)	

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:14:54
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 12:13:14
User entered 'US'	System	29 Oct 2020 13:20:22

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Dec 2020 21:04:18
User entered '2'	System	30 Oct 2020 12:13:22
User entered '1'	System	29 Oct 2020 13:20:22

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:00:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:40:41
User entered '15/Dec/2020 16:04'	System	15 Dec 2020 21:04:18

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:00:59

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 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:40:44
User entered 'I'	(b) (4), (b) (6)	15 Dec 2020 21:04:18

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'USA-US126-2020-MRNA-1273-P301000008'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'Yes (Y)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'No (N)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'No (N)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'Yes (Y)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'No (N)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'No (N)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'No (N)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'Christina'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'Kennelly'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
	(b) (4)	
User closed query 'Please update Address Fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:40:02
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:40:01
	(b) (4)	
Query 'Please update Address Fields.' answered with 'added' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 15:46:41
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:46:36
	(b) (4)	
User opened query 'Please update Address Fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:11:05
Un-reviewed for Safety.	System	15 Dec 2020 20:00:27
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:49:12
User closed query 'lease separate the city, state and zip into independent fields.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:49:09
Query 'lease separate the city, state and zip into independent fields.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 13:28:04
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:56
User opened query 'lease separate the city, state and zip into independent fields.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 13:15:24
User closed query 'Please complete address fields.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 13:15:24
Query 'Please complete address fields.' answered with 'updated' (Site from CRA).	Krishna Shah (b) (4)	19 Nov 2020 18:13:35
	(b) (4)	
User entered '6060 Piedmont Row Dr S, Charlotte, NC 28210'	Krishna Shah (b) (4)	19 Nov 2020 18:13:22
	(b) (4)	
User opened query 'Please complete address fields.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 14:28:47

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:40:04
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:46:36
	(b) (4)	
Un-reviewed for Safety.	System	15 Dec 2020 20:00:27
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:49:15
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:56
User entered empty.	Krishna Shah (b) (4)	19 Nov 2020 18:13:22
	(b) (4)	

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:40:06
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:46:36
	(b) (4)	
Un-reviewed for Safety.	System	15 Dec 2020 20:00:27
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:49:18
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:56
User entered empty.	Krishna Shah (b) (4)	19 Nov 2020 18:13:22
	(b) (4)	

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:40:07
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:46:36
	(b) (4)	
Un-reviewed for Safety.	System	15 Dec 2020 20:00:27
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:00:03
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:49:20
	(b) (4), (b) (6)	
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:56
	(b) (4)	
User entered empty.	Krishna Shah (b) (4)	19 Nov 2020 18:13:22
	(b) (4)	

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:06:31
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 14:28:28
User entered 'US'	System	17 Nov 2020 19:57:20

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Dec 2020 20:00:27
User entered '2'	System	19 Nov 2020 15:06:49
User entered '1'	System	17 Nov 2020 19:57:20

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'USA-US126-2020-MRNA-1273-P301000008'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'Yes (Y)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'No (N)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'No (N)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'Yes (Y)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'No (N)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'No (N)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'No (N)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'Christina'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'Kennelly'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
	(b) (4)	
User closed query 'Please update Address Fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:40:02
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:40:01
	(b) (4)	
Query 'Please update Address Fields.' answered with 'added' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 15:46:41
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:46:36
	(b) (4)	
User opened query 'Please update Address Fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:11:05
Un-reviewed for Safety.	System	15 Dec 2020 20:00:27
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:49:12
User closed query 'lease separate the city, state and zip into independent fields.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:49:09
Query 'lease separate the city, state and zip into independent fields.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 13:28:04
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:56
User opened query 'lease separate the city, state and zip into independent fields.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 13:15:24
User closed query 'Please complete address fields.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 13:15:24
Query 'Please complete address fields.' answered with 'updated' (Site from CRA).	Krishna Shah (b) (4)	19 Nov 2020 18:13:35
	(b) (4)	
User entered '6060 Piedmont Row Dr S, Charlotte, NC 28210'	Krishna Shah (b) (4)	19 Nov 2020 18:13:22
	(b) (4)	
User opened query 'Please complete address fields.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 14:28:47

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:40:04
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:46:36
	(b) (4)	
Un-reviewed for Safety.	System	15 Dec 2020 20:00:27
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:49:15
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:56
User entered empty.	Krishna Shah (b) (4)	19 Nov 2020 18:13:22
	(b) (4)	

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:40:06
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:46:36
	(b) (4)	
Un-reviewed for Safety.	System	15 Dec 2020 20:00:27
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:49:18
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:56
User entered empty.	Krishna Shah (b) (4)	19 Nov 2020 18:13:22
	(b) (4)	

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:40:07
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:46:36
	(b) (4)	
Un-reviewed for Safety.	System	15 Dec 2020 20:00:27
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:49:20
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:56
User entered empty.	Krishna Shah (b) (4)	19 Nov 2020 18:13:22
	(b) (4)	

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:06:31
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 14:28:28
User entered 'US'	System	17 Nov 2020 19:57:20

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Dec 2020 20:00:27
User entered '2'	System	19 Nov 2020 15:06:49
User entered '1'	System	17 Nov 2020 19:57:20

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:00:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
User entered '17/Nov/2020 19:57'	System	17 Nov 2020 19:57:20

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:00:59

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 19:58:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 15:06:31
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 14:28:28
User entered 'I'	(b) (4), (b) (6)	17 Nov 2020 19:57:20

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'USA-US126-2020-MRNA-1273-P301000008'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'Yes (Y)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'No (N)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'No (N)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'Yes (Y)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'No (N)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'No (N)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'No (N)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'Christina'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'Kennelly'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
	(b) (4)	
User closed query 'Please update Address Fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:40:02
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:40:01
	(b) (4)	
Query 'Please update Address Fields.' answered with 'added' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 15:46:41
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:46:36
	(b) (4)	
User opened query 'Please update Address Fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:11:05
Un-reviewed for Safety.	System	15 Dec 2020 20:00:27
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:49:12
User closed query 'lease separate the city, state and zip into independent fields.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:49:09
Query 'lease separate the city, state and zip into independent fields.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 13:28:04
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:56
User opened query 'lease separate the city, state and zip into independent fields.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 13:15:24
User closed query 'Please complete address fields.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 13:15:24
Query 'Please complete address fields.' answered with 'updated' (Site from CRA).	Krishna Shah (b) (4)	19 Nov 2020 18:13:35
	(b) (4)	
User entered '6060 Piedmont Row Dr S, Charlotte, NC 28210'	Krishna Shah (b) (4)	19 Nov 2020 18:13:22
	(b) (4)	
User opened query 'Please complete address fields.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 14:28:47

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:40:04
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:46:36
	(b) (4)	
Un-reviewed for Safety.	System	15 Dec 2020 20:00:27
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:49:15
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:56
User entered empty.	Krishna Shah (b) (4)	19 Nov 2020 18:13:22
	(b) (4)	

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:40:06
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:46:36
	(b) (4)	
Un-reviewed for Safety.	System	15 Dec 2020 20:00:27
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:49:18
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:56
User entered empty.	Krishna Shah (b) (4)	19 Nov 2020 18:13:22
	(b) (4)	

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:40:07
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:46:36
	(b) (4)	
Un-reviewed for Safety.	System	15 Dec 2020 20:00:27
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:49:20
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:56
User entered empty.	Krishna Shah (b) (4)	19 Nov 2020 18:13:22
	(b) (4)	

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:06:31
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 14:28:28
User entered 'US'	System	17 Nov 2020 19:57:20

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Dec 2020 20:00:27
User entered '2'	System	19 Nov 2020 15:06:49
User entered '1'	System	17 Nov 2020 19:57:20

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:00:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:46:23
User entered '19/Nov/2020 15:06'	System	19 Nov 2020 15:06:49

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:00:59

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 19:58:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:00:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:46:23
User entered 'I'	(b) (4), (b) (6)	19 Nov 2020 15:06:49

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'USA-US126-2020-MRNA-1273-P301000008'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'Yes (Y)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'No (N)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'No (N)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'Yes (Y)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'No (N)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'No (N)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'No (N)'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'Christina'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:28:28
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:57:11
User entered 'Kennelly'	System	17 Nov 2020 19:56:59

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
	(b) (4)	
User closed query 'Please update Address Fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:40:02
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:40:01
	(b) (4)	
Query 'Please update Address Fields.' answered with 'added' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 15:46:41
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:46:36
	(b) (4)	
User opened query 'Please update Address Fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:11:05
Un-reviewed for Safety.	System	15 Dec 2020 20:00:27
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:49:12
User closed query 'lease separate the city, state and zip into independent fields.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:49:09
Query 'lease separate the city, state and zip into independent fields.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 13:28:04
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:56
User opened query 'lease separate the city, state and zip into independent fields.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 13:15:24
User closed query 'Please complete address fields.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 13:15:24
Query 'Please complete address fields.' answered with 'updated' (Site from CRA).	Krishna Shah (b) (4)	19 Nov 2020 18:13:35
	(b) (4)	
User entered '6060 Piedmont Row Dr S, Charlotte, NC 28210'	Krishna Shah (b) (4)	19 Nov 2020 18:13:22
	(b) (4)	
User opened query 'Please complete address fields.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 14:28:47

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:40:04
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:46:36
	(b) (4)	
Un-reviewed for Safety.	System	15 Dec 2020 20:00:27
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:49:15
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:56
User entered empty.	Krishna Shah (b) (4)	19 Nov 2020 18:13:22
	(b) (4)	

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:40:06
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:46:36
	(b) (4)	
Un-reviewed for Safety.	System	15 Dec 2020 20:00:27
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:49:18
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:56
User entered empty.	Krishna Shah (b) (4)	19 Nov 2020 18:13:22
	(b) (4)	

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4)	05 Feb 2021 17:40:07
	(b) (4), (b) (6)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:46:36
	(b) (4)	
Un-reviewed for Safety.	System	15 Dec 2020 20:00:27
DataPoint Un-verified.	System	15 Dec 2020 20:00:27
User entered empty.	System	15 Dec 2020 20:00:27
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:00:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:49:20
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:27:56
User entered empty.	Krishna Shah (b) (4)	19 Nov 2020 18:13:22
	(b) (4)	

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:06:31
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 14:28:28
User entered 'US'	System	17 Nov 2020 19:57:20

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Dec 2020 20:00:27
User entered '2'	System	19 Nov 2020 15:06:49
User entered '1'	System	17 Nov 2020 19:57:20

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:00:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:40:17
User entered '15/Dec/2020 15:00'	System	15 Dec 2020 20:00:27

US3822003

Folder: SAE USA-US126-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:00:59

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 19:58:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:40:17
User entered 'I'	(b) (4), (b) (6)	15 Dec 2020 20:00:27