

US3822043 (Prod: Tryon Medical Partners, PLLC)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:51:52

All time stamps listed in this document are displayed in GMT

US3822043

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

Participant ID

US3822043

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

US3822043

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:22:42

Generated On: 10 Jun 2021 09:51:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 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

US3822043

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 19:22:42

Generated On: 10 Jun 2021 09:51:52

Date of Birth (MMM yyyy)	(b) (6) 1944
Age	75
Age Units	YEARS
Age (Derived)	75
Sex	Female <input checked="" type="radio"/> Male <input 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

US3822043

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 19:22:42

Generated On: 10 Jun 2021 09:51:52

Date of Informed Consent (<i>dd MMM yyyy</i>)	07 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

US3822043

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 19:22:42

Generated On: 10 Jun 2021 09:51:52

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3822043

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 19:22:42

Generated On: 10 Jun 2021 09:51:52

Were any significant conditions reported?

Yes ☒

No ☐

US3822043

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Mar 2021 17:43:42

Generated On: 10 Jun 2021 09:51:52

Condition	CHRONIC OBSTRUCTIVE LUNG DISEASE
Start date (dd MMM yyyy)	06 NOV 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3822043

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Mar 2021 17:43:42

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Mar 2021 17:43:42

Generated On: 10 Jun 2021 09:51:52

Condition	MIXED ANXIETY AND DEPRESSIVE DISORDER
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Start Year (derived)	1996
Stop Month and Year (derived)	
Stop Year (derived)	

US3822043

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Mar 2021 17:43:42

Generated On: 10 Jun 2021 09:51:52

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3822043

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Mar 2021 17:43:42

Generated On: 10 Jun 2021 09:51:52

Condition	MIXED HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3822043

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Mar 2021 17:43:42

Generated On: 10 Jun 2021 09:51:52

Condition	OSTEOPOROSIS
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)	

US3822043

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Mar 2021 17:43:42

Generated On: 10 Jun 2021 09:51:52

Condition	RESTLESS LEG SYNDROME
Start date (dd MMM yyyy)	06 NOV 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3822043

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 26 Mar 2021 17:43:42

Generated On: 10 Jun 2021 09:51:52

Condition	DIVERTICULOSIS
Start date (dd MMM yyyy)	06 NOV 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3822043

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 26 Mar 2021 17:43:42

Generated On: 10 Jun 2021 09:51:52

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1969
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 1969
Start Year (derived)	1969
Stop Month and Year (derived)	
Stop Year (derived)	

US3822043

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 26 Mar 2021 17:43:42

Generated On: 10 Jun 2021 09:51:52

Condition	BASAL CELL CARCINOMA
Start date (dd MMM yyyy)	UN UNK 2015
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)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

US3822043

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 26 Mar 2021 17:43:42

Generated On: 10 Jun 2021 09:51:52

Condition	PRE MELANOMA LEFT FOREARM
Start date (dd MMM yyyy)	UN UNK 2014
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)	UN UNK 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

US3822043

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 26 Mar 2021 17:43:42

Generated On: 10 Jun 2021 09:51:52

Condition	STAGE IV NON SMALL CELL LUNG CANCER
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3822043

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 26 Mar 2021 17:43:42

Generated On: 10 Jun 2021 09:51:52

Condition	LUNG NODULE
Start date (dd MMM yyyy)	05 FEB 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3822043

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 26 Mar 2021 17:43:42

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 26 Mar 2021 17:43:42

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 26 Mar 2021 17:43:42

Generated On: 10 Jun 2021 09:51:52

Condition	SKIN CANCER SURGERY FOR REMOVAL OF BASAL CELL CARCINOMA (MOHS SURGERY)
Start date (dd MMM yyyy)	UN UNK 2015
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)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

US3822043

Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 26 Mar 2021 17:43:42

Generated On: 10 Jun 2021 09:51:52

Condition	SKIN CANCER SURGERY FOR REMOVAL OF PRE MELONOMA ON LEFT FOREARM (MOHS SURGERY)
Start date (dd MMM yyyy)	UN UNK 2014
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)	UN UNK 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

US3822043

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 19:22:42

Generated On: 10 Jun 2021 09:51:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	07 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:16 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 13:16
Height (<i>xxx.x</i>)	60.5 in
Weight (<i>xxx.x</i>)	133 lb
BMI (<i>xxx.x</i>)	25.60064 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)	

US3822043

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:22:42

Generated On: 10 Jun 2021 09:51:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 AUG 2020

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

US3822043

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 12 Feb 2021 19:22:42

Generated On: 10 Jun 2021 09:51:52

Date of assessment (dd MMM yyyy) 07 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☒
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 1969

Date of last menstruation unknown False

US3822043

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 19:22:42

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 19:22:42

Generated On: 10 Jun 2021 09:51:52

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	

US3822043

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:22:43

Generated On: 10 Jun 2021 09:51:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 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

US3822043

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 19:22:43

Generated On: 10 Jun 2021 09:51:52

What was the date of randomization? (dd MMM yyyy) 07 AUG 2020

What was the participant's randomization number? 185196

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 ☒

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 19:22:43

Generated On: 10 Jun 2021 09:51:52

Height	ND - Not Done
Weight	ND - Not Done

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 19:22:43

Generated On: 10 Jun 2021 09:51:52

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)	07 AUG 2020
Time of assessment (00:00-23:59)	13:16 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 13:16
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 19:22:43

Generated On: 10 Jun 2021 09:51:52

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 AUG 2020
Time of assessment (00:00-23:59)	14:31 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 14:31
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3822043

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:22:43

Generated On: 10 Jun 2021 09:51:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 AUG 2020

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

US3822043

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 19:22:43

Generated On: 10 Jun 2021 09:51:52

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) 07 AUG 2020

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

Treatment Date and Time (derived) 07 AUG 2020 13:59

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

US3822043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:22:43

Generated On: 10 Jun 2021 09:51:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	07 AUG 2020
Collection time (00:00-23:59)	13:20 (24 HR)
Collection date and time (derived)	07 AUG 2020 13:20

US3822043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 19:22:43

Generated On: 10 Jun 2021 09:51:52

Collection date (dd MMM yyyy)			07 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:55	07 AUG 2020 13:55
Nasopharyngeal Swab 2	No		

US3822043

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:22:43

Generated On: 10 Jun 2021 09:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 15:12

PC Open Date & Time

07 AUG 2020 14:19

PC Close Date & Time

07 AUG 2020 16:49

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

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 97.8 °F

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

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

PC Time Stamp	07 AUG 2020 20:19
PC Open Date & Time	07 AUG 2020 17:44
PC Close Date & Time	08 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

08 AUG 2020 19:40

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:52

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 19:26

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 19:38

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:52

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

98.5 °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

11 AUG 2020 19:09

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:52

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 19:59

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:52

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

98.4 °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

13 AUG 2020 19:11

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

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

07 AUG 2020 15:13

PC Open Date & Time

07 AUG 2020 14:19

PC Close Date & Time

07 AUG 2020 16:49

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 20:20

PC Open Date & Time

07 AUG 2020 17:44

PC Close Date & Time

08 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 19:41

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:52

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

09 AUG 2020 19:26

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:52

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

10 AUG 2020 19:39

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:52

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

11 AUG 2020 19:10

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:52

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

12 AUG 2020 19:59

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:52

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

13 AUG 2020 19:12

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

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 ☐

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 15:13
PC Open Date & Time	07 AUG 2020 14:19
PC Close Date & Time	07 AUG 2020 16:49

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

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 ☐

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 20:21
PC Open Date & Time	07 AUG 2020 17:44
PC Close Date & Time	08 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:52

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 ☒

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:52

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 19:41
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:52

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

61 of 2457

EAB) (1725)

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:52

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 19:27
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

63 of 2457

EAB) (1725)

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:52

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 19:39
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

65 of 2457

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:52

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 19:10
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

67 of 2457

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:52

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 20:00
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:52

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

EAB) (1725)

69 of 2457

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:52

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 19:12
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3822043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:22:42

Generated On: 10 Jun 2021 09:51:52

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3822043

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:22:42

Generated On: 10 Jun 2021 09:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:22:42

Generated On: 10 Jun 2021 09:51:52

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3822043

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:22:42

Generated On: 10 Jun 2021 09:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:22:42

Generated On: 10 Jun 2021 09:51:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822043

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:22:42

Generated On: 10 Jun 2021 09:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:22:43

Generated On: 10 Jun 2021 09:51:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 19:22:43

Generated On: 10 Jun 2021 09:51:52

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	13:43 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 13:43
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)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 19:22:43

Generated On: 10 Jun 2021 09:51:52

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	15:10 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 15:10
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3822043

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:22:43

Generated On: 10 Jun 2021 09:51:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 SEP 2020

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

US3822043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 19:22:43

Generated On: 10 Jun 2021 09:51:52

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) 02 SEP 2020

What was the treatment time? (00:00-23:59) 14:31 (24 HR)

Treatment Date and Time (derived) 02 SEP 2020 14:31

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

US3822043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:22:43

Generated On: 10 Jun 2021 09:51:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 SEP 2020

Collection time (00:00-23:59)

14:05 (24 HR)

Collection date and time (derived)

2 SEP 2020 14:05

US3822043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 19:22:43

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:22:43

Generated On: 10 Jun 2021 09:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

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

97.4 °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

02 SEP 2020 16:00

PC Open Date & Time

02 SEP 2020 14:51

PC Close Date & Time

02 SEP 2020 17:21

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

PC Time Stamp	02 SEP 2020 20:54
PC Open Date & Time	02 SEP 2020 18:16
PC Close Date & Time	03 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:52

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

100.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 19:36

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:52

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

04 SEP 2020 19:41

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:52

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

97.0 °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

05 SEP 2020 20:15

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:52

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

06 SEP 2020 20:16

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:52

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

98.1 °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 SEP 2020 20:03

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:52

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

97.5 °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

08 SEP 2020 19:35

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 16:01

PC Open Date & Time

02 SEP 2020 14:51

PC Close Date & Time

02 SEP 2020 17:21

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 20:55

PC Open Date & Time

02 SEP 2020 18:16

PC Close Date & Time

03 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 19:37

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 19:42

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 20:16

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 20:17

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 20:03

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 19:35

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

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 ☐

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 16:01
PC Open Date & Time	02 SEP 2020 14:51
PC Close Date & Time	02 SEP 2020 17:21

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

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 ☐

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 20:55
PC Open Date & Time	02 SEP 2020 18:16
PC Close Date & Time	03 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

105 of 2457

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:52

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 19:38
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:52

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

107 of 2457

EAB) (1725)

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:52

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 19:43
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

109 of 2457

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:52

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 20:16
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:52

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

111 of 2457

EAB) (1725)

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:52

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 20:18
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

113 of 2457

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:52

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 20:03
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:52

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

115 of 2457

EAB) (1725)

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:52

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 19:36
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3822043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:22:42

Generated On: 10 Jun 2021 09:51:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822043

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:22:42

Generated On: 10 Jun 2021 09:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:22:42

Generated On: 10 Jun 2021 09:51:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822043

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:22:42

Generated On: 10 Jun 2021 09:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:22:42

Generated On: 10 Jun 2021 09:51:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822043

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:22:42

Generated On: 10 Jun 2021 09:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:22:43

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 19:22:43

Generated On: 10 Jun 2021 09:51:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	1 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	13:20 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 13:20
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	88 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3822043

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:22:43

Generated On: 10 Jun 2021 09:51:52

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.

US3822043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:22:43

Generated On: 10 Jun 2021 09:51:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 OCT 2020
Collection time (00:00-23:59)	13:39 (24 HR)
Collection date and time (derived)	1 OCT 2020 13:39

US3822043

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:22:43

Generated On: 10 Jun 2021 09:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	11 OCT 2020 14:12:12
Patient Cloud Open Date & Time	07 OCT 2020 00:01
Patient Cloud Close Date & Time	11 OCT 2020 23:59

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

14 OCT 2020 00:02:39

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	23 OCT 2020 23:12:23
Patient Cloud Open Date & Time	21 OCT 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 NOV 2020 01:48:21

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

11 NOV 2020 00:04:20

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 00:02:07

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 NOV 2020 21:58:37

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

22 NOV 2020 00:01:50

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

30 NOV 2020 22:02:41

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

06 DEC 2020 22:55:55

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

13 DEC 2020 00:02:45

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

20 DEC 2020 23:26:13

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 <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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 DEC 2020 00:06:35
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

03 JAN 2021 01:33:15

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

10 JAN 2021 00:07:08

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 08:59:42

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

24 JAN 2021 00:44:23

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

31 JAN 2021 00:30:04

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 FEB 2021 23:03:10

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 00:02:30
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

21 FEB 2021 00:02:10

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

28 FEB 2021 05:23:23

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	07 MAR 2021 00:06:59
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

14 MAR 2021 00:47:49

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

23 MAR 2021 21:07:00

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

28 MAR 2021 00:03:43

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

04 APR 2021 00:03:02

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

11 APR 2021 00:03:03

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 00:02:58

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

25 APR 2021 22:25:14

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

02 MAY 2021 00:12:59

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 ☐

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 ☐

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 <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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01
Patient Cloud Close Date & Time	24 JUN 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission	
Patient Cloud Open Date & Time	25 JUL 2021 00:01
Patient Cloud Close Date & Time	29 JUL 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 <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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 ☐

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 ☐

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

Patient Cloud Open Date & Time	15 AUG 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	19 AUG 2021 23:59
---	-------------------

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 ☐

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 ☐

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 404

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission	
Patient Cloud Open Date & Time	26 SEP 2021 00:01
Patient Cloud Close Date & Time	30 SEP 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 ☐

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 ☐

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 <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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 <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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 ☐

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

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

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 ☐

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 <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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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="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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 ☐

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 <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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 ☐

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 ☐

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 ☐

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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="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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAR 2022 00:01
Patient Cloud Close Date & Time	31 MAR 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 ☐

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 ☐

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 <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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 <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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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="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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

DAY 747

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

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

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

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

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

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

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

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

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 ☐

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 ☐

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 ☐

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 ☐

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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"/>

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3822043

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:51:52

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		28 FEB 2021 05:27:00

US3822043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:07:01

Generated On: 10 Jun 2021 09:51:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822043

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:07:01

Generated On: 10 Jun 2021 09:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:07:14

Generated On: 10 Jun 2021 09:51:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822043

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:07:14

Generated On: 10 Jun 2021 09:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:07:14

Generated On: 10 Jun 2021 09:51:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822043

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:07:14

Generated On: 10 Jun 2021 09:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:07:14

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:07:14

Generated On: 10 Jun 2021 09:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:07:14

Generated On: 10 Jun 2021 09:51:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3822043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:07:14

Generated On: 10 Jun 2021 09:51:52

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) _____

US3822043

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:07:14

Generated On: 10 Jun 2021 09:51:52

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.

US3822043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:07:14

Generated On: 10 Jun 2021 09:51:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 MAR 2021
Collection time (00:00-23:59)	14:34 (24 HR)
Collection date and time (derived)	02 MAR 2021 14:34

US3822043

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:07:14

Generated On: 10 Jun 2021 09:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822043

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:07:14

Generated On: 10 Jun 2021 09:51:52

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3822043

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:07:14

Generated On: 10 Jun 2021 09:51:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822043

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3822043

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:51:52

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3822043

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:07:14

Generated On: 10 Jun 2021 09:51:52

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

Visit date (dd MMM yyyy)	20 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
------------	---------------

US3822043

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

Form: Unblinding

Data signed: (b) (4) 11 Apr 2021 23:57:12

Generated On: 10 Jun 2021 09:51:52

Date of updated informed consent (dd MMM yyyy) 20 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) 19 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 _____

US3822043

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:07:14

Generated On: 10 Jun 2021 09:51:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 JAN 2021

Collection time (00:00-23:59)

13:26 (24 HR)

Collection date and time (derived)

20 JAN 2021 13:26

US3822043

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 20:07:14

Generated On: 10 Jun 2021 09:51:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 JAN 2021
Collection time (00:00 - 23:59)	13:35
Collection Date and Time (derived)	20 JAN 2021 13:35

US3822043

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 18:46:36

Generated On: 10 Jun 2021 09:51:52

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Mar 2021 17:47:11

Generated On: 10 Jun 2021 09:51:52

AEID	USA-US126-2020-MRNA-1273-P30 1000006
Adverse event	SMALL LYMPHOCYTIC LYMPHOMA
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)	02 OCT 2020
Start time (00:00-23:59)	11:00 (24 HR)
AE start date and time (derived)	02 OCT 2020 11:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 DEC 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	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	334 of 2457

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Mar 2021 17:47:11

Generated On: 10 Jun 2021 09:51:52

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	PER MD, THE PATIENT HAS STABLE DISEASE AT THIS TIME AND IS BEING WATCHED FOR PROGRESSION. THE PATIENT DOES NOT CURRENTLY MEET CRITERIA TO START FIRST LINE TREATMENT.
Narrative	

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Mar 2021 17:47:11

Generated On: 10 Jun 2021 09:51:52

THE PATIENT WAS SCHEDULED
FOR ROUTINE CT OF THE
CHEST TO SCREEN FOR LUNG
CANCER ON 9/5/2020. THE CT
SHOWED AN ENLARGED LET
AXILLARY LYMPH NODE THAT
WAS NEW SINCE 6/26/2018. DUE
TO THE FINDINGS THE SUBJECT
WAS SCHEDULED FOR AN
ULTRASOUND GUIDED BIOPSY.
THE BIOPSY RESULTS WERE
SMALL LYMPHOCYTIC
LYMPHOMA.

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)	

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Mar 2021 17:47:11

Generated On: 10 Jun 2021 09:51:52

AEID

Adverse event

IPSILATERAL
LYMPHADENOPATHY

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)

5 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)

06 OCT 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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

337 of 2457

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Mar 2021 17:47:11

Generated On: 10 Jun 2021 09:51:52

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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input 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	SUBJECT WAS SCHEDULED FOR AN ULTRASOUND GUIDED BIOPSY
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)	

PRODUCTION RELEASE (v12.003
EAB) (1725)

338 of 2457

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Mar 2021 17:47:11

Generated On: 10 Jun 2021 09:51:52

AEID	
Adverse event	MODERATE CENTRIOBULAR EMPHYSEMA
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)	5 SEP 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

339 of 2457

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Mar 2021 17:47:11

Generated On: 10 Jun 2021 09:51:52

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input 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)	

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 26 Mar 2021 17:47:11

Generated On: 10 Jun 2021 09:51:52

AEID	
Adverse event	MODERATE-SEVERE CORONARY ARTERIAL CALCIFICATIONS
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)	5 SEP 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"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	
341 of 2457	

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 26 Mar 2021 17:47:11

Generated On: 10 Jun 2021 09:51:52

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 <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 checked="" type="radio"/>
	Recovered/Resolved <input type="radio"/>
	Recovered/Resolved with <input type="radio"/>
	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)	

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

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

Yes ☒

No ☐

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

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

344 of 2457

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

Name of Medication SIMVASTATIN

Prophylaxis Yes ☐
No ☒

Indication MIXED HYPERLIPIDEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

346 of 2457

EAB) (1725)

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2009	
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"/>

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

Name of Medication PROLIA

Prophylaxis Yes ☐
No ☒

Indication OSTEOPOROSIS

Dose per administration 60

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

EVERY 6 MONTHS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

348 of 2457

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

Name of Medication IPRATROPIUM BROMIDE

Prophylaxis Yes ☐
No ☒

Indication ALLERGIC RHINITIS

Dose per administration 42

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

350 of 2457

EAB) (1725)

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

Name of Medication SERTRALINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION AND ANXIETY

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

352 of 2457

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1997	
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"/>

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

Name of Medication LORAZEPAM

Prophylaxis Yes ☐
No ☒

Indication RESTLESS LEG

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

354 of 2457

EAB) (1725)

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

356 of 2457

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC HEALTH

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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

358 of 2457

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2011	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

Name of Medication VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

360 of 2457

EAB) (1725)

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

Name of Medication WOMEN'S MULTI VITAMIN

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

362 of 2457

EAB) (1725)

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

Name of Medication CALCIUM

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

364 of 2457

EAB) (1725)

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

Name of Medication PROBIOTIC

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

366 of 2457

EAB) (1725)

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

Name of Medication SHINGRIX

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

368 of 2457

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

	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)		21 FEB 2019
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		21 FEB 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"/>

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

Name of Medication TRELEGY ELLIPTA

Prophylaxis Yes ☐
No ☒

Indication COPD

Dose per administration 100/62.5/25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

370 of 2457

EAB) (1725)

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 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"/>

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication COPD

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

372 of 2457

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

Name of Medication IPRATROPIUM-ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication COPD

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

374 of 2457

EAB) (1725)

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

Name of Medication BUDESONIDE

Prophylaxis Yes ☐
No ☒

Indication COPD

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

376 of 2457

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

Name of Medication DIPHTHERIA, TETANUS,
PERTUSSIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

378 of 2457

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

	Intraocular	<input type="radio"/>
	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)	01 MAY 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		1 MAY 2012
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"/>

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

380 of 2457

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

	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)		20 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)		20 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"/>

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

382 of 2457

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 20:07:14

Generated On: 10 Jun 2021 09:51:52

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3822043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 20:07:13

Generated On: 10 Jun 2021 09:51:52

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
05 SEP 2020	CT CHEST FOR LUNG CANCER SCREENING - MODERATE CENTRIOBULAR EMPHYSEMA, MODERATE-SEVERE CORONARY ARTERIAL CALCIFICATIONS. NORMAL HEART SIZE.	Medical History	
02 OCT 2020	ULTRASOUNDS GUIDED CORE BIOPSY	Adverse Event	

US3822043

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:51:52

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

US3822043

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:51:52

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 ☐

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 20:07:14

Generated On: 10 Jun 2021 09:51:52

SAEID	USA-US126-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input 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)	7

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 20:07:14

Generated On: 10 Jun 2021 09:51:52

SAEID	USA-US126-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input 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)	7
Date of submission (Pre-filled from custom function)	26/OCT/2020 21:07
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

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 20:07:14

Generated On: 10 Jun 2021 09:51:52

SAEID	USA-US126-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input 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)	7
Date of submission (Pre-filled from custom function)	28/OCT/2020 13:46
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

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 20:07:14

Generated On: 10 Jun 2021 09:51:52

SAEID	USA-US126-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input 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)	7
Date of submission (Pre-filled from custom function)	19/NOV/2020 14:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 02 Apr 2021 20:07:14

Generated On: 10 Jun 2021 09:51:52

SAEID	USA-US126-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input 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)	7
Date of submission (Pre-filled from custom function)	24/NOV/2020 19:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Data signed: (b) (4) 02 Apr 2021 20:07:14

Generated On: 10 Jun 2021 09:51:52

SAEID	USA-US126-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input 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)	7
Date of submission (Pre-filled from custom function)	22/DEC/2020 12:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Data signed: (b) (4) 02 Apr 2021 20:07:14

Generated On: 10 Jun 2021 09:51:52

SAEID	USA-US126-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input 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)	7
Date of submission (Pre-filled from custom function)	15/JAN/2021 17:10
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

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (7)

Data signed: (b) (4) 02 Apr 2021 20:07:14

Generated On: 10 Jun 2021 09:51:52

SAEID	USA-US126-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input 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)	7
Date of submission (Pre-filled from custom function)	26/JAN/2021 13:54
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

US3822043 (Prod: Tryon Medical Partners, PLLC)

US3822043

Form: Participant Creation

Generated On: 10 Jun 2021 09:51:52

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:51:25
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:49:26
User entered 'US3822043'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:14:34

US3822043

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:51:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	07 Aug 2020 18:12:19

US3822043

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '07 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:14:35

US3822043

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:51:52

[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 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4)	07 Aug 2020 18:12:19

US3822043

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:51:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'SCRN'	System	07 Aug 2020 18:12:19

US3822043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:52

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered (b) (6) 1944'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:14:35

US3822043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:52

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '75'	Kelly Woodell (b) (4)	07 Aug 2020 18:12:40

US3822043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:52

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'YEARS'	System	07 Aug 2020 18:12:40

US3822043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:52

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered '75'	System	07 Aug 2020 18:13:01

US3822043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:52

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Female (F)'	Kelly Woodell (b) (4)	07 Aug 2020 18:12:40

US3822043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:52

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kelly Woodell (b) (4)	07 Aug 2020 18:12:40

US3822043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:52

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'I'	Kelly Woodell (b) (4)	07 Aug 2020 18:12:40

US3822043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:52

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '0'	Kelly Woodell (b) (4)	07 Aug 2020 18:12:40

US3822043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:52

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '0'	Kelly Woodell (b) (4)	07 Aug 2020 18:12:40

US3822043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:52

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '0'	Kelly Woodell (b) (4)	07 Aug 2020 18:12:40

US3822043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:52

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '0'	Kelly Woodell (b) (4)	07 Aug 2020 18:12:40

US3822043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:52

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '0'	Kelly Woodell (b) (4)	07 Aug 2020 18:12:40

US3822043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:52

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	Kelly Woodell (b) (4)	07 Aug 2020 18:12:40

US3822043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:52

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '0'	Kelly Woodell (b) (4)	07 Aug 2020 18:12:40

US3822043

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:51:52

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '0'	Kelly Woodell (b) (4)	07 Aug 2020 18:12:40

US3822043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:52

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '07 Aug 2020'	Kelly Woodell (b) (4)	07 Aug 2020 18:13:01

US3822043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'Aug 2020'	System	07 Aug 2020 18:13:01

US3822043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered '2020'	System	07 Aug 2020 18:13:01

US3822043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:52

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Amendment 1 (1)'	Kelly Woodell (b) (4)	07 Aug 2020 18:13:01

US3822043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	07 Aug 2020 18:13:01

US3822043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	Kelly Woodell (b) (4)	07 Aug 2020 18:13:01

US3822043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:52

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	Kelly Woodell (b) (4)	07 Aug 2020 18:13:01

US3822043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:52

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'No (N)'	Kelly Woodell (b) (4)	07 Aug 2020 18:13:01

US3822043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:52

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:14:35

US3822043

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:51:52

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'I'	System	07 Aug 2020 18:13:06

US3822043

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	07 Aug 2020 18:13:06

US3822043

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:51:52

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:35:07
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:28:46

US3822043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 12:39:43
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 16:46:55
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 09:49:25
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive lung disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 22:30:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 22:30:22
Data point term sent to Coder	System	20 Aug 2020 22:29:28
User entered 'Chronic Obstructive Lung Disease'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:29:14

US3822043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:43:42
Signature has been broken.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:58:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '06 Nov 2018'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:29:14

US3822043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '0'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:29:14

US3822043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:29:14

US3822043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:43:42
Signature has been broken.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:55:54
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered empty.	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:29:14

US3822043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:43:42
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 17:57:26
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '0'	Kelly Woodell (b) (4)	20 Aug 2020 22:29:14

US3822043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'Nov 2018'	System	20 Aug 2020 22:29:14

US3822043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered '2018'	System	20 Aug 2020 22:29:14

US3822043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	20 Aug 2020 22:29:14

US3822043

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	20 Aug 2020 22:29:14

US3822043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User coded data point as SOC: Gastrointestinal disorders, HLG: 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) (b) (4)	20 Aug 2020 22:31:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 22:31:23
Data point term sent to Coder	System	20 Aug 2020 22:30:29
User entered 'Gastroesophageal reflux disease'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:29:43

US3822043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Un-verified.	(b) (4), (b) (6)	26 Jan 2021 15:21:17
User entered 'un UNK 2012' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 15:21:17
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '06 Nov 2018'	Kelly Woodell (b) (4)	20 Aug 2020 22:29:43

US3822043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '0'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:29:43

US3822043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:29:43

US3822043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered empty.	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:29:43

US3822043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '0'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:29:43

US3822043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'Jan 2012'	System	26 Jan 2021 15:21:17
User entered 'Nov 2018'	System	20 Aug 2020 22:29:43

US3822043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered '2012'	System	26 Jan 2021 15:21:17
User entered '2018'	System	20 Aug 2020 22:29:43

US3822043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	20 Aug 2020 22:29:43

US3822043

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	20 Aug 2020 22:29:43

US3822043

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Mixed anxiety and depressive disorder, LLT: Mixed anxiety and depressive disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 22:31:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 22:31:23
Data point term sent to Coder	System	20 Aug 2020 22:30:30
User entered 'Mixed anxiety and depressive disorder'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:30:11

US3822043

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Un-verified.	Krishna Shah (b) (4)	22 Dec 2020 15:00:25
User entered 'UN UNK 1996' reason for change:	Krishna Shah (b) (4)	22 Dec 2020 15:00:25
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '06 Nov 2018'	Kelly Woodell (b) (4)	20 Aug 2020 22:30:11

US3822043

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '0'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:30:11

US3822043

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:30:11

US3822043

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered empty.	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:30:11

US3822043

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '0'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:30:11

US3822043

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'Jan 1996'	System	22 Dec 2020 15:00:25
User entered 'Nov 2018'	System	20 Aug 2020 22:30:11

US3822043

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered '1996'	System	22 Dec 2020 15:00:25
User entered '2018'	System	20 Aug 2020 22:30:11

US3822043

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	20 Aug 2020 22:30:11

US3822043

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	20 Aug 2020 22:30:11

US3822043

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 12:39:55
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 16:47:17
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 09:49:34
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 22:31:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 22:31:23
Data point term sent to Coder	System	20 Aug 2020 22:30:30
User entered 'Hypertension'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:30:29

US3822043

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered 'UN UNK 2015'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:30:29

US3822043

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '0'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:30:29

US3822043

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:30:29

US3822043

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered empty.	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:30:29

US3822043

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '0'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:30:29

US3822043

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'Jan 2015'	System	20 Aug 2020 22:30:29

US3822043

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered '2015'	System	20 Aug 2020 22:30:29

US3822043

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	20 Aug 2020 22:30:29

US3822043

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	20 Aug 2020 22:30:29

US3822043

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:51:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Metabolic and nutritional disorders congenital, HLT: Inborn errors of lipid metabolism, PT: Type V hyperlipidaemia, LLT: Mixed hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 22:32:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 22:32:24
Data point term sent to Coder	System	20 Aug 2020 22:31:31
User entered 'Mixed Hyperlipidemia'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:30:52

US3822043

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Un-verified.	(b) (4), (b) (6)	26 Jan 2021 15:18:16
User entered 'un UNK 2009' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 15:18:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '06 Nov 2018'	Kelly Woodell (b) (4)	20 Aug 2020 22:30:52

US3822043

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '0'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:30:52

US3822043

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:51:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:30:52

US3822043

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered empty.	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:30:52

US3822043

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:51:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '0'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:30:52

US3822043

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'Jan 2009'	System	26 Jan 2021 15:18:16
User entered 'Nov 2018'	System	20 Aug 2020 22:30:52

US3822043

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered '2009'	System	26 Jan 2021 15:18:16
User entered '2018'	System	20 Aug 2020 22:30:52

US3822043

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	20 Aug 2020 22:30:52

US3822043

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	20 Aug 2020 22:30:52

US3822043

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:51:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 22:32:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 22:32:24
Data point term sent to Coder	System	20 Aug 2020 22:31:32
User entered 'Osteoporosis'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:31:12

US3822043

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Un-verified.	Krishna Shah (b) (4)	22 Dec 2020 14:58:16
User entered 'UN UNK 2017' reason for change: Data Entry Error	Krishna Shah (b) (4)	22 Dec 2020 14:58:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '06 Nov 2018'	Kelly Woodell (b) (4)	20 Aug 2020 22:31:12

US3822043

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '0'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:31:12

US3822043

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:51:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:31:12

US3822043

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered empty.	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:31:12

US3822043

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:51:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '0'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:31:12

US3822043

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'Jan 2017'	System	22 Dec 2020 14:58:16
User entered 'Nov 2018'	System	20 Aug 2020 22:31:12

US3822043

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered '2017'	System	22 Dec 2020 14:58:16
User entered '2018'	System	20 Aug 2020 22:31:12

US3822043

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	20 Aug 2020 22:31:12

US3822043

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	20 Aug 2020 22:31:12

US3822043

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:51:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User coded data point as SOC: Nervous system disorders, HLT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless leg syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 22:33:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 22:33:25
Data point term sent to Coder	System	20 Aug 2020 22:32:32
User entered 'Restless leg syndrome'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:31:42

US3822043

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '06 Nov 2018'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:31:42

US3822043

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '0'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:31:42

US3822043

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:51:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:31:42

US3822043

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered empty.	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:31:42

US3822043

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:51:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '0'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:31:42

US3822043

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'Nov 2018'	System	20 Aug 2020 22:31:42

US3822043

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered '2018'	System	20 Aug 2020 22:31:42

US3822043

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	20 Aug 2020 22:31:42

US3822043

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	20 Aug 2020 22:31:42

US3822043

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:51:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User coded data point as SOC: Gastrointestinal disorders, HLGT: Diverticular disorders, HLT: Diverticula, PT: Diverticulum, LLT: Diverticulosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 22:33:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 22:33:25
Data point term sent to Coder	System	20 Aug 2020 22:32:32
User entered 'Diverticulosis'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:32:18

US3822043

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '06 Nov 2018'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:32:18

US3822043

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '0'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:32:18

US3822043

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:51:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:32:18

US3822043

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered empty.	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:32:18

US3822043

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:51:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '0'	Kelly Woodell (b) (4) (b) (4)	20 Aug 2020 22:32:18

US3822043

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'Nov 2018'	System	20 Aug 2020 22:32:18

US3822043

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered '2018'	System	20 Aug 2020 22:32:18

US3822043

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	20 Aug 2020 22:32:18

US3822043

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	20 Aug 2020 22:32:18

US3822043

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:51:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 15:09:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 15:09:39
Data point term sent to Coder	System	20 Oct 2020 15:09:23
User entered 'Post menopausal'	(b) (4), (b) (6)	20 Oct 2020 15:09:16

US3822043

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered 'un UNK 1969'	(b) (4), (b) (6)	20 Oct 2020 15:09:16

US3822043

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 15:09:16

US3822043

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:51:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 15:09:16

US3822043

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 15:09:16

US3822043

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:51:52

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User closed query 'Per Hem/Onc records 21OCT2020, per past HM on page 4 of 16, subject is noted as having Stage IV NSCLC, bone mets, Stage IIA invasive mammary carcinoma R breast, bioprosthetic mitral valve porcine. Kindly confirm if these should ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:39:19
Query 'Per Hem/Onc records 21OCT2020, per past HM on page 4 of 16, subject is noted as having Stage IV NSCLC, bone mets, Stage IIA invasive mammary carcinoma R breast, bioprosthetic mitral valve porcine. Kindly confirm if these should ' answered with 'added' (Site from CRA).	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 19:58:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:56:39
User closed query 'Per source subject is noted as having a history of Pre melanoma left forearm, kindly consider adding to EDC.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:56:13
User closed query 'Per Hem/Onc source note dated 21OCT2020, subject has history of a pulmonary nodule. Kindly consider adding to EDC. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:56:03
User closed query 'Per source subject is noted as having history of Basil cell carcinoma on nose. Kindly consider adding to EDC. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:55:56
Query 'Per Hem/Onc source note dated 21OCT2020, subject has history of a pulmonary nodule. Kindly consider adding to EDC. ' answered with 'added' (Site from CRA).	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 19:52:52
Query 'Per source subject is noted as having a history of Pre melanoma left forearm, kindly consider adding to EDC.' answered with 'added' (Site from CRA).	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 19:52:40
Query 'Per source subject is noted as having history of Basil cell carcinoma on nose. Kindly consider adding to EDC. ' answered with 'added' (Site from CRA).	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 19:52:35

US3822043

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:51:52

Stop date completely unknown

Audit	User	Time (GMT)
User opened query 'Per Hem/Onc records 21OCT2020, per past HM on page 4 of 16, subject is noted as having Stage IV NSCLC, bone mets, Stage IIA invasive mammary carcinoma R breast, bioprosthetic mitral valve porcine. Kindly confirm if these should ' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 21:20:18
User opened query 'Per Hem/Onc source note dated 21OCT2020, subject has history of a pulmonary nodule. Kindly consider adding to EDC. ' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 21:09:09
User opened query 'Per source subject is noted as having a history of Pre melanoma left forearm, kindly consider adding to EDC.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 20:36:02
User opened query 'Per source subject is noted as having history of Basil cell carcinoma on nose. Kindly consider consider adding to EDC. ' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 20:34:32
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 15:09:16

US3822043

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'Jan 1969'	System	20 Oct 2020 15:09:16

US3822043

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered '1969'	System	20 Oct 2020 15:09:16

US3822043

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	20 Oct 2020 15:09:16

US3822043

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	20 Oct 2020 15:09:16

US3822043

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:51:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 19:54:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 19:54:46
Data point term sent to Coder	System	10 Nov 2020 19:53:45
User entered 'Basal cell carcinoma'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 19:53:12

US3822043

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered 'un UNK 2015'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 19:53:12

US3822043

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '0'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 19:53:12

US3822043

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:51:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	10 Nov 2020 19:53:22
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	10 Nov 2020 19:53:12
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 19:53:12

US3822043

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User closed query 'Per CDM Re-Query: Site response noted. Per CCGs page 37 of CCGs, the associated surgical procedure should be recorded in a separate log line. Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 12:02:10
Query 'Per CDM Re-Query: Site response noted. Per CCGs page 37 of CCGs, the associated surgical procedure should be recorded in a separate log line. Please review and reconcile. Thank you. ' answered with 'Added, see MH log line 18' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 12:49:40
User opened query 'Per CDM Re-Query: Site response noted. Per CCGs page 37 of CCGs, the associated surgical procedure should be recorded in a separate log line. Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 12:47:50
User closed query 'Per CDM: Condition has end-date, however, related treatment to resolve this condition is expected and has not been recorded. Per v5.0 of CCGs, please confirm condition is not present at time of signing Informed Consent. If condition is not ongoing, kindly record related treatment, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 12:47:50
Query 'Per CDM: Condition has end-date, however, related treatment to resolve this condition is expected and has not been recorded. Per v5.0 of CCGs, please confirm condition is not present at time of signing Informed Consent. If condition is not ongoing, kindly record related treatment, else clarify. Thank you.' answered with 'Treatment was it was surgically removed' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	16 Mar 2021 14:00:58
User opened query 'Per CDM: Condition has end-date, however, related treatment to resolve this condition is expected and has not been recorded. Per v5.0 of CCGs, please confirm condition is not present at time of signing Informed Consent. If condition is not ongoing, kindly record related treatment, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 16:06:35
User signature succeeded.	Christina Kennelly (b) (4) (b) (4)	12 Feb 2021 19:22:44

US3822043

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered 'un UNK 2015' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 19:53:22
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 19:53:12

US3822043

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:51:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '0'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 19:53:12

US3822043

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'Jan 2015'	System	10 Nov 2020 19:53:12

US3822043

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered '2015'	System	10 Nov 2020 19:53:12

US3822043

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'Jan 2015'	System	10 Nov 2020 19:53:22
User entered empty.	System	10 Nov 2020 19:53:12

US3822043

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered '2015'	System	10 Nov 2020 19:53:22
User entered empty.	System	10 Nov 2020 19:53:12

US3822043

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:51:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Cutaneous neoplasms benign, HLT: Skin neoplasms benign, PT: Juvenile melanoma benign, LLT: Benign melanoma - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 06:56:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 06:56:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:56:39
Data point term sent to Coder	System	10 Nov 2020 19:54:46
User entered 'Pre melanoma left forearm'	Kelly Woodell (b) (4)	10 Nov 2020 19:53:47

US3822043

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered 'un UNK 2014'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 19:53:47

US3822043

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '0'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 19:53:47

US3822043

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:51:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 19:53:47

US3822043

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User closed query 'Per CDM Re-Query: Site response noted. Per CCGs page 37 of CCGs, the associated surgical procedure should be recorded in a separate log line. Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 12:02:51
Query 'Per CDM Re-Query: Site response noted. Per CCGs page 37 of CCGs, the associated surgical procedure should be recorded in a separate log line. Please review and reconcile. Thank you. ' answered with 'Procedure added to MH, see log line 20' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 12:51:01
User opened query 'Per CDM Re-Query: Site response noted. Per CCGs page 37 of CCGs, the associated surgical procedure should be recorded in a separate log line. Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 12:48:19
User closed query 'Per CDM: Condition has end-date, however, related treatment to resolve this condition is expected and has not been recorded. Per v5.0 of CCGs, please confirm condition is not present at time of signing Informed Consent. If condition is not ongoing, kindly record related treatment, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 12:48:19
Query 'Per CDM: Condition has end-date, however, related treatment to resolve this condition is expected and has not been recorded. Per v5.0 of CCGs, please confirm condition is not present at time of signing Informed Consent. If condition is not ongoing, kindly record related treatment, else clarify. Thank you.' answered with 'Treatment was surgery' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	16 Mar 2021 14:04:45
User opened query 'Per CDM: Condition has end-date, however, related treatment to resolve this condition is expected and has not been recorded. Per v5.0 of CCGs, please confirm condition is not present at time of signing Informed Consent. If condition is not ongoing, kindly record related treatment, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 16:07:28

US3822043

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered 'un UNK 2014'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 19:53:47

US3822043

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:51:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:39
User entered '0'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 19:53:47

US3822043

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'Jan 2014'	System	10 Nov 2020 19:53:47

US3822043

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered '2014'	System	10 Nov 2020 19:53:47

US3822043

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'Jan 2014'	System	10 Nov 2020 19:53:47

US3822043

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered '2014'	System	10 Nov 2020 19:53:47

US3822043

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:51:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:36:12
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Respiratory and mediastinal neoplasms malignant and unspecified, HLT: Non-small cell neoplasms malignant of the respiratory tract cell type specified, PT: Non-small cell lung cancer stage IV, LLT: Non-small cell lung cancer stage IV - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 07:03:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 07:03:58
Data point term sent to Coder	System	10 Nov 2020 19:58:54
User entered 'Stage IV non small cell lung cancer'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 19:58:33

US3822043

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:36:14
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 19:58:33

US3822043

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:36:16
User entered 'I'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 19:58:33

US3822043

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:51:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:36:19
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 19:58:33

US3822043

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:36:21
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 19:58:33

US3822043

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:51:52

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User closed query 'Per CDM: Condition has end-date, however, related treatment to resolve this condition is expected and has not been recorded. Per v5.0 of CCGs, please confirm condition is not present at time of signing Informed Consent. If condition is not ongoing, kindly record related treatment, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 12:48:28
Query 'Per CDM: Condition has end-date, however, related treatment to resolve this condition is expected and has not been recorded. Per v5.0 of CCGs, please confirm condition is not present at time of signing Informed Consent. If condition is not ongoing, kindly record related treatment, else clarify. Thank you.' answered with 'Subject has not received any treatment at this time' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	16 Mar 2021 14:05:24
User opened query 'Per CDM: Condition has end-date, however, related treatment to resolve this condition is expected and has not been recorded. Per v5.0 of CCGs, please confirm condition is not present at time of signing Informed Consent. If condition is not ongoing, kindly record related treatment, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 16:08:03
User signature succeeded.	Christina Kennelly (b) (4) (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 14:36:23
User entered '1'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 19:58:33

US3822043

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	10 Nov 2020 19:58:33

US3822043

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	10 Nov 2020 19:58:33

US3822043

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	10 Nov 2020 19:58:33

US3822043

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	10 Nov 2020 19:58:33

US3822043

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:51:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:36:46
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 14:36:37
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory tract disorders NEC, PT: Pulmonary mass, LLT: Lung nodule - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:01:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:01:45
Data point term sent to Coder	System	10 Nov 2020 20:01:00
User entered 'Lung nodule'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:00:05

US3822043

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:36:48
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 14:36:40
User entered '05 Feb 2014'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:00:05

US3822043

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '0'	Kelly Woodell (b) (4)	10 Nov 2020 20:00:05

US3822043

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:51:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Nov 2020 20:00:05

US3822043

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	Kelly Woodell (b) (4)	10 Nov 2020 20:00:05

US3822043

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:51:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '0'	Kelly Woodell (b) (4)	10 Nov 2020 20:00:05

US3822043

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'Feb 2014'	System	10 Nov 2020 20:00:05

US3822043

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered '2014'	System	10 Nov 2020 20:00:05

US3822043

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	10 Nov 2020 20:00:05

US3822043

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	10 Nov 2020 20:00:05

US3822043

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:51:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:36:53
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Metastases, HLT: Metastases to specified sites, PT: Metastases to bone, LLT: Bone metastases - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:54:40
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 21:54:40
Data point term sent to Coder	System	10 Nov 2020 20:01:00
User entered 'Bone Metastasis'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:00:30

US3822043

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:36:55
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:00:30

US3822043

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:36:59
User entered 'I'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:00:30

US3822043

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:51:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:37:02
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:00:30

US3822043

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:37:05
User entered empty.	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 20:00:30

US3822043

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:51:52

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User closed query 'Per CDM: Condition has end-date, however, related treatment to resolve this condition is expected and has not been recorded. Per v5.0 of CCGs, please confirm condition is not present at time of signing Informed Consent. If condition is not ongoing, kindly record related treatment, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 12:48:38
Query 'Per CDM: Condition has end-date, however, related treatment to resolve this condition is expected and has not been recorded. Per v5.0 of CCGs, please confirm condition is not present at time of signing Informed Consent. If condition is not ongoing, kindly record related treatment, else clarify. Thank you.' answered with 'Treatment unknown' (Site from DM).	Kelly Woodell (b) (4)	16 Mar 2021 14:06:14
User opened query 'Per CDM: Condition has end-date, however, related treatment to resolve this condition is expected and has not been recorded. Per v5.0 of CCGs, please confirm condition is not present at time of signing Informed Consent. If condition is not ongoing, kindly record related treatment, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 16:08:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 14:37:06
User entered 'I'	Kelly Woodell (b) (4)	10 Nov 2020 20:00:30

US3822043

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	10 Nov 2020 20:00:30

US3822043

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	10 Nov 2020 20:00:30

US3822043

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	10 Nov 2020 20:00:30

US3822043

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	10 Nov 2020 20:00:30

US3822043

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:51:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:43:42
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 14:06:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 14:06:59
Data point term sent to Coder	System	23 Feb 2021 14:05:49
User entered 'ALLERGIC RHINITIS'	(b) (4), (b) (6)	23 Feb 2021 14:05:04

US3822043

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:43:42
User entered 'UN UNK 2012'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:05:04

US3822043

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:43:42
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:05:04

US3822043

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:51:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:43:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:05:04

US3822043

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:43:42
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:05:04

US3822043

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:51:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:43:42
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:05:04

US3822043

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'Jan 2012'	System	23 Feb 2021 14:05:04

US3822043

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered '2012'	System	23 Feb 2021 14:05:04

US3822043

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	23 Feb 2021 14:05:04

US3822043

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered empty.	System	23 Feb 2021 14:05:04

US3822043

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:51:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin lesion excisions, PT: Skin neoplasm excision, LLT: Basal cell carcinoma skin excision - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 21:18:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 21:18:16
User signature succeeded.	Christina Kennelly (b) (4) (b) (4)	26 Mar 2021 17:43:42
Data point term sent to Coder	System	24 Mar 2021 12:48:19
User entered 'SKIN CANCER SURGERY FOR REMOVAL OF BASAL CELL CARCINOMA (MOHS SURGERY)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 12:47:39
Data point term sent to Coder	System	24 Mar 2021 12:47:18
User entered 'SKIN CANCER SURGERY FOR REMOVAL OF BASAL CELL CARCINOMA'	(b) (4), (b) (6)	24 Mar 2021 12:47:17

US3822043

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:43:42
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 12:47:17

US3822043

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:43:42
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 12:47:17

US3822043

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:51:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:43:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 12:47:17

US3822043

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:43:42
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 12:47:17

US3822043

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:51:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:43:42
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 12:47:17

US3822043

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'Jan 2015'	System	24 Mar 2021 12:47:17

US3822043

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered '2015'	System	24 Mar 2021 12:47:17

US3822043

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'Jan 2015'	System	24 Mar 2021 12:47:17

US3822043

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered '2015'	System	24 Mar 2021 12:47:17

US3822043

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:51:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin lesion excisions, PT: Skin neoplasm excision, LLT: Skin malignant melanoma excision - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 21:21:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 21:21:26
User signature succeeded.	Christina Kennelly (b) (4) (b) (4)	26 Mar 2021 17:43:42
Data point term sent to Coder	System	24 Mar 2021 12:49:20
User entered 'SKIN CANCER SURGERY FOR REMOVAL OF PRE MELONOMA ON LEFT FOREARM (MOHS SURGERY)'	(b) (4), (b) (6)	24 Mar 2021 12:49:19

US3822043

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:43:42
User entered 'Un UNK 2014'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 12:49:19

US3822043

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:43:42
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 12:49:19

US3822043

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:51:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:43:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 12:49:19

US3822043

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:43:42
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 12:49:19

US3822043

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:51:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:43:42
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 12:49:19

US3822043

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'Jan 2014'	System	24 Mar 2021 12:49:19

US3822043

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered '2014'	System	24 Mar 2021 12:49:19

US3822043

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'Jan 2014'	System	24 Mar 2021 12:49:19

US3822043

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered '2014'	System	24 Mar 2021 12:49:19

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	20 Aug 2020 22:34:11

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '07 Aug 2020'	Kelly Woodell (b) (4)	20 Aug 2020 22:34:11

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '13:16'	Kelly Woodell (b) (4)	20 Aug 2020 22:34:11

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered '07 Aug 2020 13:16'	System	20 Aug 2020 22:34:11

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '60.5' in	Kelly Woodell (b) (4)	20 Aug 2020 22:34:11
DataPoint set to visible.	System	07 Aug 2020 18:13:06

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '133' lb	Kelly Woodell (b) (4)	20 Aug 2020 22:34:11
DataPoint set to visible.	System	07 Aug 2020 18:13:06

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
Amendment Manager: User entered '25.60064'	System	16 Sep 2020 23:47:36
User entered '25.6'	System	20 Aug 2020 22:34:11
DataPoint set to visible.	System	07 Aug 2020 18:13:06

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'kg/m2'	System	20 Aug 2020 22:34:11
DataPoint set to visible.	System	07 Aug 2020 18:13:06

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Krishna Shah (b) (4)	29 Oct 2020 19:49:14
User entered '98.2' F	(b) (4) Kelly Woodell (b) (4)	20 Aug 2020 22:34:11

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty; reason for change Data Entry Error	(b) (4) Krishna Shah (b) (4)	29 Oct 2020 19:49:14
User entered 'Oral (Oral)'	(b) (4) Kelly Woodell (b) (4)	20 Aug 2020 22:34:11

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	Kelly Woodell (b) (4)	20 Aug 2020 22:34:11

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Krishna Shah (b) (4)	29 Oct 2020 19:49:14
User entered '78'	(b) (4) Kelly Woodell (b) (4)	20 Aug 2020 22:34:11

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'bpm'	System	20 Aug 2020 22:34:11

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Oct 2020 19:49:14
User entered '20'	Kelly Woodell (b) (4)	20 Aug 2020 22:34:11

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'breaths/min'	System	20 Aug 2020 22:34:11

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Oct 2020 19:49:14
User entered '110'	Kelly Woodell (b) (4)	20 Aug 2020 22:34:11

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'mmHg'	System	20 Aug 2020 22:34:11

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Oct 2020 19:49:14
User entered '70'	Kelly Woodell (b) (4)	20 Aug 2020 22:34:11

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User entered 'mmHg'	System	20 Aug 2020 22:34:11

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27

US3822043

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27

US3822043

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	21 Aug 2020 00:24:04

US3822043

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 12:11:30
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	02 Sep 2020 18:34:32
User entered '07 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	21 Aug 2020 00:24:04

US3822043

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:51:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '07 Aug 2020'	Kelly Woodell (b) (4)	21 Aug 2020 00:25:06

US3822043

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:51:52

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'No (N)'	Kelly Woodell (b) (4)	21 Aug 2020 00:25:06

US3822043

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:51:52

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 10:04:58
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 15:09:32
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 06:40:18
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Kelly Woodell (b) (4) (b) (4)	21 Aug 2020 00:25:06

US3822043

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:51:52

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	Kelly Woodell (b) (4)	21 Aug 2020 00:25:06

US3822043

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:51:52

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	Kelly Woodell (b) (4)	21 Aug 2020 00:25:06

US3822043

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:51:52

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '0'	Kelly Woodell (b) (4)	21 Aug 2020 00:25:06

US3822043

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:51:52

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'UN UNK 1969'	Kelly Woodell (b) (4)	21 Aug 2020 00:25:06

US3822043

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:51:52

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '0'	Kelly Woodell (b) (4)	21 Aug 2020 00:25:06

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:52

[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 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'No (N)'	Kelly Woodell (b) (4)	21 Aug 2020 00:25:39

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:52

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 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'No (N)'	Kelly Woodell (b) (4)	21 Aug 2020 00:25:39

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:52

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 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'No (N)'	Kelly Woodell (b) (4)	21 Aug 2020 00:25:39

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:52

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 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'No (N)'	Kelly Woodell (b) (4)	21 Aug 2020 00:25:39

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:52

[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 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'No (N)'	Kelly Woodell (b) (4)	21 Aug 2020 00:25:39

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:52

[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 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'No (N)'	Kelly Woodell (b) (4)	21 Aug 2020 00:25:39

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:52

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 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'No (N)'	Kelly Woodell (b) (4)	21 Aug 2020 00:25:39

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:52

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 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'No (N)'	Kelly Woodell (b) (4)	21 Aug 2020 00:25:39

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:52

[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 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'No (N)'	Kelly Woodell (b) (4)	21 Aug 2020 00:25:39

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:52

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 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'No (N)'	Kelly Woodell (b) (4)	21 Aug 2020 00:25:39

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:52

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 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'No (N)'	Kelly Woodell (b) (4)	21 Aug 2020 00:25:39

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:52

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'No (N)'	Kelly Woodell (b) (4)	21 Aug 2020 00:25:39

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:52

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	Kelly Woodell (b) (4)	21 Aug 2020 00:25:39

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:52

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'I'	Kelly Woodell (b) (4)	21 Aug 2020 00:25:39

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:52

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '0'	Kelly Woodell (b) (4)	21 Aug 2020 00:25:39

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:52

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 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '0'	Kelly Woodell (b) (4)	21 Aug 2020 00:25:39

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:52

[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 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '0'	Kelly Woodell (b) (4)	21 Aug 2020 00:25:39

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:52

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 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '0'	Kelly Woodell (b) (4)	21 Aug 2020 00:25:39

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '0'	Kelly Woodell (b) (4)	21 Aug 2020 00:25:39

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:52

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '0'	Kelly Woodell (b) (4)	21 Aug 2020 00:25:39

US3822043

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:51:52

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:27:27
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	Kelly Woodell (b) (4)	21 Aug 2020 00:25:39

US3822043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:51:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	07 Aug 2020 18:13:35

US3822043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '07 Aug 2020'	Kelly Woodell (b) (4)	07 Aug 2020 18:13:35

US3822043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4)	07 Aug 2020 18:13:35

US3822043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:51:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'VISIT1'	System	07 Aug 2020 18:13:35

US3822043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '07 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:14:36

US3822043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:52

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 02:54:30
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:54:30
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 17:14:36
User entered '185196' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:14:36

US3822043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:14:36

US3822043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:52

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)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	07 Aug 2020 18:14:25

US3822043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:52

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)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'No (N)'	Kelly Woodell (b) (4)	07 Aug 2020 18:14:25

US3822043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'No (N)'	Kelly Woodell (b) (4)	07 Aug 2020 18:14:25

US3822043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:52

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'No (N)'	Kelly Woodell (b) (4)	07 Aug 2020 18:14:25

US3822043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:51:52

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'No (N)'	Kelly Woodell (b) (4)	07 Aug 2020 18:14:25

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:52

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 11:21:39
Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' answered with 'ND' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 15:09:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 15:09:50
User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:09:57
User entered '60.5' in	Kelly Woodell (b) (4) (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 15:09:50
User entered '133' lb	Kelly Woodell (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:52

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 11:21:39
Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' answered with 'ND' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 15:09:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 15:09:50
User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:09:57
User entered '60.5' in	Kelly Woodell (b) (4) (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 15:09:50
User entered '133' lb	Kelly Woodell (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User accepted default value 'Pre-Dose (PREDOSE)'	Kelly Woodell (b) (4) (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '07 Aug 2020'	Kelly Woodell (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '13:16'	Kelly Woodell (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered '07 Aug 2020 13:16'	System	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '98.2' F	Kelly Woodell (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Oral (Oral)'	Kelly Woodell (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	Kelly Woodell (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '78'	Kelly Woodell (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'bpm'	System	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '20'	Kelly Woodell (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'breaths/min'	System	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '110'	Kelly Woodell (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'mmHg'	System	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '70'	Kelly Woodell (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'mmHg'	System	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:52

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 11:21:39
Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' answered with 'ND' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 15:09:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 15:09:50
User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:09:57
User entered '60.5' in	Kelly Woodell (b) (4) (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:51:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 15:09:50
User entered '133' lb	Kelly Woodell (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User accepted default value 'Post-Dose (POSTDOSE)'	Kelly Woodell (b) (4) (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '07 Aug 2020'	Kelly Woodell (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 02:54:26
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 collected 30 mins post dose per protocol' (Site from System).	Kelly Woodell (b) (4)	21 Aug 2020 00:28:01
User opened 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).	System	21 Aug 2020 00:27:31
User entered '14:31'	Kelly Woodell (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered '07 Aug 2020 14:31'	System	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '97.8' F	Kelly Woodell (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Oral (Oral)'	Kelly Woodell (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	Kelly Woodell (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '75'	Kelly Woodell (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'bpm'	System	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '16'	Kelly Woodell (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'breaths/min'	System	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '116'	Kelly Woodell (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'mmHg'	System	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '70'	Kelly Woodell (b) (4)	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'mmHg'	System	21 Aug 2020 00:27:31

US3822043

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	21 Aug 2020 00:28:17

US3822043

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '07 Aug 2020'	Kelly Woodell (b) (4)	21 Aug 2020 00:28:17

US3822043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	07 Aug 2020 18:14:44

US3822043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	Kelly Woodell (b) (4)	07 Aug 2020 18:14:44

US3822043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:52

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)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	Kelly Woodell (b) (4)	07 Aug 2020 18:14:44

US3822043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:52

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'MRNA-1273 OR PLACEBO'	System	07 Aug 2020 18:14:44

US3822043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '07 Aug 2020'	Kelly Woodell (b) (4)	07 Aug 2020 18:14:44

US3822043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '13:59'	Kelly Woodell (b) (4)	07 Aug 2020 18:14:44

US3822043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:52

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered '07 Aug 2020 13:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Left Arm (LEFT ARM)'	Kelly Woodell (b) (4)	07 Aug 2020 18:14:44

US3822043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:52

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'ONCE'	System	07 Aug 2020 18:14:44

US3822043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:51:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'INTRAMUSCULAR'	System	07 Aug 2020 18:14:44

US3822043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	21 Aug 2020 00:28:57

US3822043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '07 Aug 2020'	Kelly Woodell (b) (4)	21 Aug 2020 00:28:57

US3822043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:52

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '13:20'	Kelly Woodell (b) (4)	21 Aug 2020 00:28:57

US3822043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered '07 Aug 2020 13:20'	System	21 Aug 2020 00:28:57

US3822043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:51:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '07 Aug 2020'	Kelly Woodell (b) (4)	21 Aug 2020 00:29:11

US3822043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:51:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelly Woodell (b) (4) (b) (4)	21 Aug 2020 00:29:11

US3822043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:51:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	21 Aug 2020 00:29:11

US3822043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:51:52

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '13:55'	Kelly Woodell (b) (4)	21 Aug 2020 00:29:11

US3822043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:51:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered '07 Aug 2020 13:55'	System	21 Aug 2020 00:29:11

US3822043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:51:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelly Woodell (b) (4) (b) (4)	21 Aug 2020 00:29:11

US3822043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:51:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'No (N)'	Kelly Woodell (b) (4)	21 Aug 2020 00:29:11

US3822043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:51:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	Kelly Woodell (b) (4)	21 Aug 2020 00:29:11

US3822043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:51:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered empty.	System	21 Aug 2020 00:29:11

US3822043

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	21 Aug 2020 00:29:15

US3822043

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'I'	System	21 Aug 2020 00:29:15

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:11:57', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '00b2b152-94b6-44c7-82c4-41b498af17d7'	System	07 Aug 2020 19:12:28
User entered 'Yes (Y)'	System	07 Aug 2020 19:12:28

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:12:05', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '00b2b152-94b6-44c7-82c4-41b498af17d7' User entered '97.8'	System	07 Aug 2020 19:12:28
	System	07 Aug 2020 19:12:28

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:12:17', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '00b2b152-94b6-44c7-82c4-41b498af17d7'	System	07 Aug 2020 19:12:28
User entered 'No (N)'	System	07 Aug 2020 19:12:28

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:12:25', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '00b2b152-94b6-44c7-82c4-41b498af17d7'	System	07 Aug 2020 19:12:28
User entered '07 Aug 2020 15:12'	System	07 Aug 2020 19:12:28

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '07 Aug 2020 14:19'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '07 Aug 2020 16:49'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:18:42', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '81f7e4e7-93e8-4659-b688-5a9dae15ab91' User entered 'Yes (Y)'	System	08 Aug 2020 00:19:18
	System	08 Aug 2020 00:19:18

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:18:52', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '81f7e4e7-93e8-4659-b688-5a9dae15ab91' User entered '97.8'	System	08 Aug 2020 00:19:18
	System	08 Aug 2020 00:19:18

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:18:59', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '81f7e4e7-93e8-4659-b688-5a9dae15ab91'	System	08 Aug 2020 00:19:18
User entered 'No (N)'	System	08 Aug 2020 00:19:18

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:19:13', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '81f7e4e7-93e8-4659-b688-5a9dae15ab91' User entered '07 Aug 2020 20:19'	System	08 Aug 2020 00:19:18
	System	08 Aug 2020 00:19:18

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '07 Aug 2020 17:44'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 2'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:38:26', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '828d8bbd-3fbb-4e78-89e3-4519da1e8588' User entered 'Yes (Y)'	System	08 Aug 2020 23:40:31
	System	08 Aug 2020 23:40:31

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:39:57', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '828d8bbd-3fbb-4e78-89e3-4519da1e8588' User entered '98.6'	System	08 Aug 2020 23:40:31
	System	08 Aug 2020 23:40:31

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:40:06', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '828d8bbd-3fbb-4e78-89e3-4519da1e8588'	System	08 Aug 2020 23:40:31
User entered 'Yes (Y)'	System	08 Aug 2020 23:40:31

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
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 'Per day 8 Phone call no medication was taken' (Site from System).	(b) (4), (b) (6)	27 Aug 2020 17:40:10
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:40:16', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '828d8bbd-3fbb-4e78-89e3-4519da1e8588' User entered '1'	Kelly Woodell (b) (4)	26 Aug 2020 02:07:17
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	08 Aug 2020 23:40:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:40:16', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '828d8bbd-3fbb-4e78-89e3-4519da1e8588' User entered '1'	System	08 Aug 2020 23:40:31
User entered '1'	System	08 Aug 2020 23:40:31

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:52

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:40:16', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '828d8bbd-3fbb-4e78-89e3-4519da1e8588' User entered '0'	System	08 Aug 2020 23:40:31
	System	08 Aug 2020 23:40:31

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:40:27', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '828d8bbd-3fbb-4e78-89e3-4519da1e8588'	System	08 Aug 2020 23:40:31
User entered '08 Aug 2020 19:40'	System	08 Aug 2020 23:40:31

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 3'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:26:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'dde7c304-9529-4246-bf9d-f876a1d9ece9' User entered 'Yes (Y)'	System	09 Aug 2020 23:26:25
	System	09 Aug 2020 23:26:25

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:26:08', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'dde7c304-9529-4246-bf9d-f876a1d9ece9' User entered '98.5'	System	09 Aug 2020 23:26:25
	System	09 Aug 2020 23:26:25

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:26:13', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'dde7c304-9529-4246-bf9d-f876a1d9ece9'	System	09 Aug 2020 23:26:25
User entered 'No (N)'	System	09 Aug 2020 23:26:25

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:26:20', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'dde7c304-9529-4246-bf9d-f876a1d9ece9'	System	09 Aug 2020 23:26:25
User entered '09 Aug 2020 19:26'	System	09 Aug 2020 23:26:25

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 4'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:38:05', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e129f8bf-c0ae-4748-9798-6bdf93477a92'	System	10 Aug 2020 23:38:31
User entered 'Yes (Y)'	System	10 Aug 2020 23:38:31

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:38:13', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e129f8bf-c0ae-4748-9798-6bdf93477a92'	System	10 Aug 2020 23:38:31
User entered '98.3'	System	10 Aug 2020 23:38:31

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:38:18', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e129f8bf-c0ae-4748-9798-6bdf93477a92'	System	10 Aug 2020 23:38:31
User entered 'No (N)'	System	10 Aug 2020 23:38:31

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:38:26', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e129f8bf-c0ae-4748-9798-6bdf93477a92'	System	10 Aug 2020 23:38:31
User entered '10 Aug 2020 19:38'	System	10 Aug 2020 23:38:31

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 5'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:09:47', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '295389d1-605e-4649-a82f-a5db5f406323' User entered 'Yes (Y)'	System	11 Aug 2020 23:10:17
	System	11 Aug 2020 23:10:17

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:09:52', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '295389d1-605e-4649-a82f-a5db5f406323' User entered '98.5'	System	11 Aug 2020 23:10:17
	System	11 Aug 2020 23:10:17

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:09:56', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '295389d1-605e-4649-a82f-a5db5f406323' User entered 'No (N)'	System	11 Aug 2020 23:10:17
	System	11 Aug 2020 23:10:17

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:09:59', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '295389d1-605e-4649-a82f-a5db5f406323' User entered '11 Aug 2020 19:09'	System	11 Aug 2020 23:10:17
	System	11 Aug 2020 23:10:17

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 6'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T19:59:04', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '78069720-283a-429e-879b-e89020aaeb29' User entered 'Yes (Y)'	System	12 Aug 2020 23:59:24
	System	12 Aug 2020 23:59:24

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T19:59:10', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '78069720-283a-429e-879b-e89020aaeb29' User entered '98.6'	System	12 Aug 2020 23:59:24
	System	12 Aug 2020 23:59:24

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T19:59:16', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '78069720-283a-429e-879b-e89020aaeb29'	System	12 Aug 2020 23:59:24
User entered 'No (N)'	System	12 Aug 2020 23:59:24

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T19:59:19', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '78069720-283a-429e-879b-e89020aaeb29' User entered '12 Aug 2020 19:59'	System	12 Aug 2020 23:59:24
	System	12 Aug 2020 23:59:24

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 7'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:11:33', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '8d7e26e9-2eee-4e3a-83ae-619b11035e80' User entered 'Yes (Y)'	System	13 Aug 2020 23:11:59
	System	13 Aug 2020 23:11:59

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:11:44', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '8d7e26e9-2eee-4e3a-83ae-619b11035e80' User entered '98.4'	System	13 Aug 2020 23:11:59
	System	13 Aug 2020 23:11:59

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:11:48', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '8d7e26e9-2eee-4e3a-83ae-619b11035e80' User entered 'No (N)'	System	13 Aug 2020 23:11:59
	System	13 Aug 2020 23:11:59

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:11:52', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '8d7e26e9-2eee-4e3a-83ae-619b11035e80' User entered '13 Aug 2020 19:11'	System	13 Aug 2020 23:11:59
	System	13 Aug 2020 23:11:59

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:12:52', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0185d42b-aca3-4655-ac38-5bcf89636952'	System	07 Aug 2020 19:13:16
User entered 'None (1)'	System	07 Aug 2020 19:13:16

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:12:55', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0185d42b-aca3-4655-ac38-5bcf89636952'	System	07 Aug 2020 19:13:16
User entered 'No (N)'	System	07 Aug 2020 19:13:16

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:12:58', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0185d42b-aca3-4655-ac38-5bcf89636952'	System	07 Aug 2020 19:13:16
User entered 'No (N)'	System	07 Aug 2020 19:13:16

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:13:06', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0185d42b-aca3-4655-ac38-5bcf89636952'	System	07 Aug 2020 19:13:16
User entered 'None (1)'	System	07 Aug 2020 19:13:16

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:13:13', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0185d42b-aca3-4655-ac38-5bcf89636952' User entered '07 Aug 2020 15:13'	System	07 Aug 2020 19:13:16
	System	07 Aug 2020 19:13:16

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '07 Aug 2020 14:19'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '07 Aug 2020 16:49'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:19:38', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'cbe75e25-2961-44f6-b4f5-540c9949093f' User entered 'Does not interfere with activity (2)'	System	08 Aug 2020 00:20:21
	System	08 Aug 2020 00:20:21

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:19:42', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'cbe75e25-2961-44f6-b4f5-540c9949093f' User entered 'No (N)'	System	08 Aug 2020 00:20:21
	System	08 Aug 2020 00:20:21

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:19:50', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'cbe75e25-2961-44f6-b4f5-540c9949093f' User entered 'No (N)'	System	08 Aug 2020 00:20:21
	System	08 Aug 2020 00:20:21

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:20:02', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'cbe75e25-2961-44f6-b4f5-540c9949093f' User entered 'None (1)'	System	08 Aug 2020 00:20:21
	System	08 Aug 2020 00:20:21

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:20:19', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'cbe75e25-2961-44f6-b4f5-540c9949093f' User entered '07 Aug 2020 20:20'	System	08 Aug 2020 00:20:21
	System	08 Aug 2020 00:20:21

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '07 Aug 2020 17:44'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 2'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:40:37', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '810d5382-5e53-4e02-b66d-919c76a72eb1' User entered 'Does not interfere with activity (2)'	System	08 Aug 2020 23:41:13
	System	08 Aug 2020 23:41:13

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:40:41', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '810d5382-5e53-4e02-b66d-919c76a72eb1'	System	08 Aug 2020 23:41:13
User entered 'No (N)'	System	08 Aug 2020 23:41:13

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:40:51', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '810d5382-5e53-4e02-b66d-919c76a72eb1' User entered 'No (N)'	System	08 Aug 2020 23:41:13
	System	08 Aug 2020 23:41:13

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:41:05', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '810d5382-5e53-4e02-b66d-919c76a72eb1'	System	08 Aug 2020 23:41:13
User entered 'None (1)'	System	08 Aug 2020 23:41:13

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:41:08', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '810d5382-5e53-4e02-b66d-919c76a72eb1' User entered '08 Aug 2020 19:41'	System	08 Aug 2020 23:41:13
	System	08 Aug 2020 23:41:13

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 3'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:26:35', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '3764a53c-68a5-4981-9f87-a812a813ac28'	System	09 Aug 2020 23:26:54
User entered 'Does not interfere with activity (2)'	System	09 Aug 2020 23:26:54

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:26:38', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '3764a53c-68a5-4981-9f87-a812a813ac28' User entered 'No (N)'	System	09 Aug 2020 23:26:54
	System	09 Aug 2020 23:26:54

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:26:42', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '3764a53c-68a5-4981-9f87-a812a813ac28' User entered 'No (N)'	System	09 Aug 2020 23:26:54
	System	09 Aug 2020 23:26:54

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:26:47', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '3764a53c-68a5-4981-9f87-a812a813ac28' User entered 'None (1)'	System	09 Aug 2020 23:26:54
	System	09 Aug 2020 23:26:54

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:26:50', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '3764a53c-68a5-4981-9f87-a812a813ac28' User entered '09 Aug 2020 19:26'	System	09 Aug 2020 23:26:54
	System	09 Aug 2020 23:26:54

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 4'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:38:31', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '15ba1843-cdab-4323-8f1c-be6660c1900a' User entered 'None (1)'	System	10 Aug 2020 23:39:04
	System	10 Aug 2020 23:39:04

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:38:35', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '15ba1843-cdab-4323-8f1c-be6660c1900a' User entered 'No (N)'	System	10 Aug 2020 23:39:04
	System	10 Aug 2020 23:39:04

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:38:42', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '15ba1843-cdab-4323-8f1c-be6660c1900a' User entered 'No (N)'	System	10 Aug 2020 23:39:04
	System	10 Aug 2020 23:39:04

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:38:57', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '15ba1843-cdab-4323-8f1c-be6660c1900a' User entered 'None (1)'	System	10 Aug 2020 23:39:04
	System	10 Aug 2020 23:39:04

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:39:01', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '15ba1843-cdab-4323-8f1c-be6660c1900a' User entered '10 Aug 2020 19:39'	System	10 Aug 2020 23:39:04
	System	10 Aug 2020 23:39:04

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 5'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:10:05', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e2ca7043-e104-4c2f-b573-011ffb622554'	System	11 Aug 2020 23:10:23
User entered 'None (1)'	System	11 Aug 2020 23:10:23

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:10:08', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e2ca7043-e104-4c2f-b573-011ffb622554'	System	11 Aug 2020 23:10:23
User entered 'No (N)'	System	11 Aug 2020 23:10:23

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:10:12', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e2ca7043-e104-4c2f-b573-011ffb622554'	System	11 Aug 2020 23:10:23
User entered 'No (N)'	System	11 Aug 2020 23:10:23

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:10:15', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e2ca7043-e104-4c2f-b573-011ffb622554'	System	11 Aug 2020 23:10:23
User entered 'None (1)'	System	11 Aug 2020 23:10:23

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:10:18', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e2ca7043-e104-4c2f-b573-011ffb622554'	System	11 Aug 2020 23:10:23
User entered '11 Aug 2020 19:10'	System	11 Aug 2020 23:10:23

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 6'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T19:59:22', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'be3e61e3-c489-4a00-bb00-91e0b9a9b7a5' User entered 'None (1)'	System	12 Aug 2020 23:59:47
	System	12 Aug 2020 23:59:47

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T19:59:26', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'be3e61e3-c489-4a00-bb00-91e0b9a9b7a5' User entered 'No (N)'	System	12 Aug 2020 23:59:47
	System	12 Aug 2020 23:59:47

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T19:59:32', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'be3e61e3-c489-4a00-bb00-91e0b9a9b7a5' User entered 'No (N)'	System	12 Aug 2020 23:59:47
	System	12 Aug 2020 23:59:47

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T19:59:38', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'be3e61e3-c489-4a00-bb00-91e0b9a9b7a5' User entered 'None (1)'	System	12 Aug 2020 23:59:47
	System	12 Aug 2020 23:59:47

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T19:59:43', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'be3e61e3-c489-4a00-bb00-91e0b9a9b7a5' User entered '12 Aug 2020 19:59'	System	12 Aug 2020 23:59:47
	System	12 Aug 2020 23:59:47

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 7'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:11:56', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '52fed148-e57b-464e-90b2-4c937f077331' User entered 'None (1)'	System	13 Aug 2020 23:12:19
	System	13 Aug 2020 23:12:19

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:12:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '52fed148-e57b-464e-90b2-4c937f077331' User entered 'No (N)'	System	13 Aug 2020 23:12:19
	System	13 Aug 2020 23:12:19

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:12:03', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '52fed148-e57b-464e-90b2-4c937f077331' User entered 'No (N)'	System	13 Aug 2020 23:12:19
	System	13 Aug 2020 23:12:19

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:12:08', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '52fed148-e57b-464e-90b2-4c937f077331' User entered 'None (1)'	System	13 Aug 2020 23:12:19
	System	13 Aug 2020 23:12:19

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:12:11', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '52fed148-e57b-464e-90b2-4c937f077331' User entered '13 Aug 2020 19:12'	System	13 Aug 2020 23:12:19
	System	13 Aug 2020 23:12:19

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:13:23', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2ca4f4f1-6f01-4898-ae6b-556ab0d2cca0' User entered 'None (0)'	System	07 Aug 2020 19:13:52
	System	07 Aug 2020 19:13:52

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:13:30', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2ca4f4f1-6f01-4898-ae6b-556ab0d2cca0' User entered 'None (0)'	System	07 Aug 2020 19:13:52
	System	07 Aug 2020 19:13:52

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:13:33', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2ca4f4f1-6f01-4898-ae6b-556ab0d2cca0' User entered 'None (0)'	System	07 Aug 2020 19:13:52
	System	07 Aug 2020 19:13:52

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:13:36', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2ca4f4f1-6f01-4898-ae6b-556ab0d2cca0' User entered 'None (0)'	System	07 Aug 2020 19:13:52
	System	07 Aug 2020 19:13:52

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:13:39', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2ca4f4f1-6f01-4898-ae6b-556ab0d2cca0' User entered 'None (0)'	System	07 Aug 2020 19:13:52
	System	07 Aug 2020 19:13:52

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:13:41', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2ca4f4f1-6f01-4898-ae6b-556ab0d2cca0' User entered 'None (0)'	System	07 Aug 2020 19:13:52
	System	07 Aug 2020 19:13:52

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:13:46', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2ca4f4f1-6f01-4898-ae6b-556ab0d2cca0' User entered 'No (N)'	System	07 Aug 2020 19:13:52
	System	07 Aug 2020 19:13:52

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T15:13:49', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2ca4f4f1-6f01-4898-ae6b-556ab0d2cca0' User entered '07 Aug 2020 15:13'	System	07 Aug 2020 19:13:52
	System	07 Aug 2020 19:13:52

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '07 Aug 2020 14:19'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '07 Aug 2020 16:49'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:20:25', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0ff5c7fb-b660-4039-b322-e62b54bdd9d4' User entered 'None (0)'	System	08 Aug 2020 00:21:18
	System	08 Aug 2020 00:21:18

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:21:08', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0ff5c7fb-b660-4039-b322-e62b54bdd9d4'	System	08 Aug 2020 00:21:18
User entered 'No interference with activity (1)'	System	08 Aug 2020 00:21:18

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:20:36', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0ff5c7fb-b660-4039-b322-e62b54bdd9d4' User entered 'None (0)'	System	08 Aug 2020 00:21:18
	System	08 Aug 2020 00:21:18

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:20:39', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0ff5c7fb-b660-4039-b322-e62b54bdd9d4' User entered 'None (0)'	System	08 Aug 2020 00:21:18
	System	08 Aug 2020 00:21:18

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:20:42', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0ff5c7fb-b660-4039-b322-e62b54bdd9d4' User entered 'None (0)'	System	08 Aug 2020 00:21:18
	System	08 Aug 2020 00:21:18

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:20:45', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0ff5c7fb-b660-4039-b322-e62b54bdd9d4' User entered 'None (0)'	System	08 Aug 2020 00:21:18
	System	08 Aug 2020 00:21:18

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:20:56', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0ff5c7fb-b660-4039-b322-e62b54bdd9d4' User entered 'No (N)'	System	08 Aug 2020 00:21:18
	System	08 Aug 2020 00:21:18

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-07T20:21:17', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0ff5c7fb-b660-4039-b322-e62b54bdd9d4' User entered '07 Aug 2020 20:21'	System	08 Aug 2020 00:21:18
	System	08 Aug 2020 00:21:18

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '07 Aug 2020 17:44'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 2'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:41:13', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '41281f7f-75f8-4ad5-ac09-e764749b03a8' User entered 'None (0)'	System	08 Aug 2020 23:41:48
	System	08 Aug 2020 23:41:48

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:41:21', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '41281f7f-75f8-4ad5-ac09-e764749b03a8'	System	08 Aug 2020 23:41:48
User entered 'No interference with activity (1)'	System	08 Aug 2020 23:41:48

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:41:25', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '41281f7f-75f8-4ad5-ac09-e764749b03a8' User entered 'None (0)'	System	08 Aug 2020 23:41:48
	System	08 Aug 2020 23:41:48

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:41:27', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '41281f7f-75f8-4ad5-ac09-e764749b03a8' User entered 'None (0)'	System	08 Aug 2020 23:41:48
	System	08 Aug 2020 23:41:48

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:41:30', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '41281f7f-75f8-4ad5-ac09-e764749b03a8' User entered 'None (0)'	System	08 Aug 2020 23:41:48
	System	08 Aug 2020 23:41:48

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:41:33', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '41281f7f-75f8-4ad5-ac09-e764749b03a8' User entered 'None (0)'	System	08 Aug 2020 23:41:48
	System	08 Aug 2020 23:41:48

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:41:37', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '41281f7f-75f8-4ad5-ac09-e764749b03a8' User entered 'No (N)'	System	08 Aug 2020 23:41:48
	System	08 Aug 2020 23:41:48

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-08T19:41:44', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '41281f7f-75f8-4ad5-ac09-e764749b03a8' User entered '08 Aug 2020 19:41'	System	08 Aug 2020 23:41:48
	System	08 Aug 2020 23:41:48

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 3'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:26:57', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '47d133b0-77ed-4947-9296-3243acba7a3c' User entered 'None (0)'	System	09 Aug 2020 23:27:21
	System	09 Aug 2020 23:27:21

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:27:01', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '47d133b0-77ed-4947-9296-3243acba7a3c' User entered 'None (0)'	System	09 Aug 2020 23:27:21
	System	09 Aug 2020 23:27:21

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:27:05', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '47d133b0-77ed-4947-9296-3243acba7a3c' User entered 'None (0)'	System	09 Aug 2020 23:27:21
	System	09 Aug 2020 23:27:21

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:27:07', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '47d133b0-77ed-4947-9296-3243acba7a3c' User entered 'None (0)'	System	09 Aug 2020 23:27:21
	System	09 Aug 2020 23:27:21

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:27:09', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '47d133b0-77ed-4947-9296-3243acba7a3c' User entered 'None (0)'	System	09 Aug 2020 23:27:21
	System	09 Aug 2020 23:27:21

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:27:12', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '47d133b0-77ed-4947-9296-3243acba7a3c' User entered 'None (0)'	System	09 Aug 2020 23:27:21
	System	09 Aug 2020 23:27:21

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:27:15', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '47d133b0-77ed-4947-9296-3243acba7a3c' User entered 'No (N)'	System	09 Aug 2020 23:27:21
	System	09 Aug 2020 23:27:21

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-09T19:27:18', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '47d133b0-77ed-4947-9296-3243acba7a3c' User entered '09 Aug 2020 19:27'	System	09 Aug 2020 23:27:21
	System	09 Aug 2020 23:27:21

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 4'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:39:05', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'c0cb3fe7-de24-4e50-8f16-ff346e6860eb' User entered 'None (0)'	System	10 Aug 2020 23:39:30
	System	10 Aug 2020 23:39:30

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:39:07', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'c0cb3fe7-de24-4e50-8f16-ff346e6860eb' User entered 'None (0)'	System	10 Aug 2020 23:39:30
	System	10 Aug 2020 23:39:30

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:39:11', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'c0cb3fe7-de24-4e50-8f16-ff346e6860eb' User entered 'None (0)'	System	10 Aug 2020 23:39:30
	System	10 Aug 2020 23:39:30

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:39:13', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'c0cb3fe7-de24-4e50-8f16-ff346e6860eb' User entered 'None (0)'	System	10 Aug 2020 23:39:30
	System	10 Aug 2020 23:39:30

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:39:15', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'c0cb3fe7-de24-4e50-8f16-ff346e6860eb' User entered 'None (0)'	System	10 Aug 2020 23:39:30
	System	10 Aug 2020 23:39:30

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:39:18', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'c0cb3fe7-de24-4e50-8f16-ff346e6860eb' User entered 'None (0)'	System	10 Aug 2020 23:39:30
	System	10 Aug 2020 23:39:30

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:39:22', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'c0cb3fe7-de24-4e50-8f16-ff346e6860eb' User entered 'No (N)'	System	10 Aug 2020 23:39:30
	System	10 Aug 2020 23:39:30

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-10T19:39:25', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'c0cb3fe7-de24-4e50-8f16-ff346e6860eb' User entered '10 Aug 2020 19:39'	System	10 Aug 2020 23:39:30
	System	10 Aug 2020 23:39:30

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 5'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:10:22', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '9b319c28-b969-465c-b7cc-43b36821f65e' User entered 'None (0)'	System	11 Aug 2020 23:10:44
	System	11 Aug 2020 23:10:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:10:25', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '9b319c28-b969-465c-b7cc-43b36821f65e' User entered 'None (0)'	System	11 Aug 2020 23:10:44
	System	11 Aug 2020 23:10:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:10:27', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '9b319c28-b969-465c-b7cc-43b36821f65e' User entered 'None (0)'	System	11 Aug 2020 23:10:44
	System	11 Aug 2020 23:10:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:10:29', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '9b319c28-b969-465c-b7cc-43b36821f65e' User entered 'None (0)'	System	11 Aug 2020 23:10:44
	System	11 Aug 2020 23:10:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:10:31', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '9b319c28-b969-465c-b7cc-43b36821f65e' User entered 'None (0)'	System	11 Aug 2020 23:10:44
	System	11 Aug 2020 23:10:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:10:33', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '9b319c28-b969-465c-b7cc-43b36821f65e' User entered 'None (0)'	System	11 Aug 2020 23:10:44
	System	11 Aug 2020 23:10:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:10:36', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '9b319c28-b969-465c-b7cc-43b36821f65e' User entered 'No (N)'	System	11 Aug 2020 23:10:44
	System	11 Aug 2020 23:10:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-11T19:10:39', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '9b319c28-b969-465c-b7cc-43b36821f65e' User entered '11 Aug 2020 19:10'	System	11 Aug 2020 23:10:44
	System	11 Aug 2020 23:10:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 6'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T19:59:51', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '54754328-0201-4b35-a575-f4759b7bfdd8' User entered 'None (0)'	System	13 Aug 2020 00:00:12
	System	13 Aug 2020 00:00:12

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T19:59:54', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '54754328-0201-4b35-a575-f4759b7bfdd8' User entered 'None (0)'	System	13 Aug 2020 00:00:12
	System	13 Aug 2020 00:00:12

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T19:59:56', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '54754328-0201-4b35-a575-f4759b7bfdd8' User entered 'None (0)'	System	13 Aug 2020 00:00:12
	System	13 Aug 2020 00:00:12

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T19:59:58', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '54754328-0201-4b35-a575-f4759b7bfdd8' User entered 'None (0)'	System	13 Aug 2020 00:00:12
	System	13 Aug 2020 00:00:12

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T20:00:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '54754328-0201-4b35-a575-f4759b7bfdd8' User entered 'None (0)'	System	13 Aug 2020 00:00:12
	System	13 Aug 2020 00:00:12

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T20:00:02', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '54754328-0201-4b35-a575-f4759b7bfdd8' User entered 'None (0)'	System	13 Aug 2020 00:00:12
	System	13 Aug 2020 00:00:12

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T20:00:06', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '54754328-0201-4b35-a575-f4759b7bfdd8' User entered 'No (N)'	System	13 Aug 2020 00:00:12
	System	13 Aug 2020 00:00:12

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-12T20:00:09', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '54754328-0201-4b35-a575-f4759b7bfdd8' User entered '12 Aug 2020 20:00'	System	13 Aug 2020 00:00:12
	System	13 Aug 2020 00:00:12

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 7'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:12:17', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '767074bf-157b-49ba-8ca2-8ec4239384ee' User entered 'None (0)'	System	13 Aug 2020 23:12:38
	System	13 Aug 2020 23:12:38

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:12:19', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '767074bf-157b-49ba-8ca2-8ec4239384ee' User entered 'None (0)'	System	13 Aug 2020 23:12:38
	System	13 Aug 2020 23:12:38

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:12:21', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '767074bf-157b-49ba-8ca2-8ec4239384ee' User entered 'None (0)'	System	13 Aug 2020 23:12:38
	System	13 Aug 2020 23:12:38

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:12:23', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '767074bf-157b-49ba-8ca2-8ec4239384ee' User entered 'None (0)'	System	13 Aug 2020 23:12:38
	System	13 Aug 2020 23:12:38

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:12:25', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '767074bf-157b-49ba-8ca2-8ec4239384ee' User entered 'None (0)'	System	13 Aug 2020 23:12:38
	System	13 Aug 2020 23:12:38

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:12:27', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '767074bf-157b-49ba-8ca2-8ec4239384ee' User entered 'None (0)'	System	13 Aug 2020 23:12:38
	System	13 Aug 2020 23:12:38

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:12:31', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '767074bf-157b-49ba-8ca2-8ec4239384ee' User entered 'No (N)'	System	13 Aug 2020 23:12:38
	System	13 Aug 2020 23:12:38

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-08-13T19:12:34', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '767074bf-157b-49ba-8ca2-8ec4239384ee' User entered '13 Aug 2020 19:12'	System	13 Aug 2020 23:12:38
	System	13 Aug 2020 23:12:38

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 18:14:44

US3822043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	21 Aug 2020 00:30:37

US3822043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '17 Aug 2020'	Kelly Woodell (b) (4)	21 Aug 2020 00:30:37

US3822043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4)	21 Aug 2020 00:30:37

US3822043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	Kelly Woodell (b) (4)	21 Aug 2020 00:30:37

US3822043

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	21 Aug 2020 00:30:40

US3822043

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'I'	System	21 Aug 2020 00:30:40

US3822043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	02 Sep 2020 00:14:31

US3822043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '24 Aug 2020'	Kelly Woodell (b) (4)	02 Sep 2020 00:14:31

US3822043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4)	02 Sep 2020 00:14:31

US3822043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	Kelly Woodell (b) (4)	02 Sep 2020 00:14:31

US3822043

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	02 Sep 2020 00:14:34

US3822043

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'I'	System	02 Sep 2020 00:14:34

US3822043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	02 Sep 2020 00:14:44

US3822043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '31 Aug 2020'	Kelly Woodell (b) (4)	02 Sep 2020 00:14:44

US3822043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4)	02 Sep 2020 00:14:44

US3822043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	Kelly Woodell (b) (4)	02 Sep 2020 00:14:44

US3822043

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	02 Sep 2020 00:14:47

US3822043

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'I'	System	02 Sep 2020 00:14:47

US3822043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	02 Sep 2020 18:34:25

US3822043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User closed query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Sep 2020 11:09:07
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Date is correct as is. Per protocol there is a -3/+7 day window and the visit falls within that window.' (Site from System).	Kelly Woodell (b) (4) (b) (4)	02 Sep 2020 18:34:46
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	02 Sep 2020 18:34:32
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Sep 2020 18:34:32
User entered '02 Sep 2020' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	02 Sep 2020 18:34:32
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Sep 2020 18:34:25
User entered '02 Sep 202' (non-conformant).	Kelly Woodell (b) (4) (b) (4)	02 Sep 2020 18:34:25

US3822043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4)	02 Sep 2020 18:34:25

US3822043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'VISIT2'	System	02 Sep 2020 18:34:25

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User accepted default value 'Pre-Dose (PREDOSE)'	Krishna Shah (b) (4) (b) (4)	06 Oct 2020 20:16:17

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Krishna Shah (b) (4)	06 Oct 2020 20:16:17

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '2 Sep 2020'	Krishna Shah (b) (4)	06 Oct 2020 20:16:17

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '13:43'	Krishna Shah (b) (4)	06 Oct 2020 20:16:17

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered '2 Sep 2020 13:43'	System	06 Oct 2020 20:16:17

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '98.5' F	Krishna Shah (b) (4)	06 Oct 2020 20:16:17

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Oral (Oral)'	Krishna Shah (b) (4)	06 Oct 2020 20:16:17

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	Krishna Shah (b) (4)	06 Oct 2020 20:16:17

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '86'	Krishna Shah (b) (4)	06 Oct 2020 20:16:17

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'bpm'	System	06 Oct 2020 20:16:17

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '18'	Krishna Shah (b) (4)	06 Oct 2020 20:16:17

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'breaths/min'	System	06 Oct 2020 20:16:17

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '130'	Krishna Shah (b) (4)	06 Oct 2020 20:16:17

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'mmHg'	System	06 Oct 2020 20:16:17

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '84'	Krishna Shah (b) (4)	06 Oct 2020 20:16:17

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:51:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'mmHg'	System	06 Oct 2020 20:16:17

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User accepted default value 'Post-Dose (POSTDOSE)'	Krishna Shah (b) (4) (b) (4)	06 Oct 2020 20:17:37

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Krishna Shah (b) (4)	06 Oct 2020 20:17:37

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '2 Sep 2020'	Krishna Shah (b) (4)	06 Oct 2020 20:17:37

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '15:10'	Krishna Shah (b) (4)	06 Oct 2020 20:17:37

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered '2 Sep 2020 15:10'	System	06 Oct 2020 20:17:37

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '99.1' F	Krishna Shah (b) (4)	06 Oct 2020 20:17:37

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Oral (Oral)'	Krishna Shah (b) (4)	06 Oct 2020 20:17:37

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	Krishna Shah (b) (4)	06 Oct 2020 20:17:37

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '81'	Krishna Shah (b) (4)	06 Oct 2020 20:17:37

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'bpm'	System	06 Oct 2020 20:17:37

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '18'	Krishna Shah (b) (4)	06 Oct 2020 20:17:37

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'breaths/min'	System	06 Oct 2020 20:17:37

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '125'	Krishna Shah (b) (4)	06 Oct 2020 20:17:37

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'mmHg'	System	06 Oct 2020 20:17:37

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '76'	Krishna Shah (b) (4)	06 Oct 2020 20:17:37

US3822043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:51:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'mmHg'	System	06 Oct 2020 20:17:37

US3822043

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	02 Sep 2020 18:35:01

US3822043

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '02 Sep 2020'	Kelly Woodell (b) (4)	02 Sep 2020 18:35:01

US3822043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	02 Sep 2020 18:35:19

US3822043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	Kelly Woodell (b) (4)	02 Sep 2020 18:35:19

US3822043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:52

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)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	Kelly Woodell (b) (4)	02 Sep 2020 18:35:19

US3822043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:52

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 18:35:19

US3822043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '02 Sep 2020'	Kelly Woodell (b) (4)	02 Sep 2020 18:35:19

US3822043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '14:31'	Kelly Woodell (b) (4)	02 Sep 2020 18:35:19

US3822043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:52

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered '02 Sep 2020 14:31'	System	02 Sep 2020 18:35:19

US3822043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Left Arm (LEFT ARM)'	Kelly Woodell (b) (4)	02 Sep 2020 18:35:19

US3822043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:52

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'ONCE'	System	02 Sep 2020 18:35:19

US3822043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:51:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 18:35:19

US3822043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Krishna Shah (b) (4)	06 Oct 2020 20:18:21

US3822043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '2 Sep 2020'	Krishna Shah (b) (4)	06 Oct 2020 20:18:21

US3822043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:52

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '14:05'	Krishna Shah (b) (4)	06 Oct 2020 20:18:21

US3822043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered '2 Sep 2020 14:05'	System	06 Oct 2020 20:18:21

US3822043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:51:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '2 Sep 2020'	Krishna Shah (b) (4)	06 Oct 2020 20:18:38

US3822043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:51:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Krishna Shah (b) (4) (b) (4)	06 Oct 2020 20:18:38

US3822043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:51:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Krishna Shah (b) (4)	06 Oct 2020 20:18:38

US3822043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:51:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '14:14'	Krishna Shah (b) (4)	06 Oct 2020 20:18:38

US3822043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:51:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered '2 Sep 2020 14:14'	System	06 Oct 2020 20:18:38

US3822043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:51:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Krishna Shah (b) (4) (b) (4)	06 Oct 2020 20:18:38

US3822043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:51:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'No (N)'	Krishna Shah (b) (4)	06 Oct 2020 20:18:38

US3822043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:51:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	Krishna Shah (b) (4)	06 Oct 2020 20:18:38

US3822043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:51:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered empty.	System	06 Oct 2020 20:18:38

US3822043

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	02 Sep 2020 18:35:29

US3822043

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'I'	System	02 Sep 2020 18:35:29

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	02 Sep 2020 18:35:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:00:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'eea885fd-0bed-4322-9d91-51f7b74f56ea' User entered 'Yes (Y)'	System	02 Sep 2020 20:00:26
	System	02 Sep 2020 20:00:26

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:00:08', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'eea885fd-0bed-4322-9d91-51f7b74f56ea' User entered '97.4'	System	02 Sep 2020 20:00:26
	System	02 Sep 2020 20:00:26

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:00:12', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'eea885fd-0bed-4322-9d91-51f7b74f56ea' User entered 'No (N)'	System	02 Sep 2020 20:00:26
	System	02 Sep 2020 20:00:26

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:00:22', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'eea885fd-0bed-4322-9d91-51f7b74f56ea' User entered '02 Sep 2020 16:00'	System	02 Sep 2020 20:00:26
	System	02 Sep 2020 20:00:26

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '02 Sep 2020 14:51'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '02 Sep 2020 17:21'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	02 Sep 2020 18:35:19
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:53:50', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '175d3d55-401f-42a4-a80b-08dc86b1f40a' User entered 'Yes (Y)'	System	03 Sep 2020 00:54:15
	System	03 Sep 2020 00:54:15

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:54:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '175d3d55-401f-42a4-a80b-08dc86b1f40a' User entered '97.9'	System	03 Sep 2020 00:54:15
	System	03 Sep 2020 00:54:15

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:54:05', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '175d3d55-401f-42a4-a80b-08dc86b1f40a' User entered 'No (N)'	System	03 Sep 2020 00:54:15
	System	03 Sep 2020 00:54:15

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:54:11', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '175d3d55-401f-42a4-a80b-08dc86b1f40a' User entered '02 Sep 2020 20:54'	System	03 Sep 2020 00:54:15
	System	03 Sep 2020 00:54:15

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '02 Sep 2020 18:16'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	02 Sep 2020 18:35:19
User entered 'Day 2'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:35:40', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'ad8c12e6-4987-42d6-90bd-2cf4182be6d2' User entered 'Yes (Y)'	System	03 Sep 2020 23:36:08
	System	03 Sep 2020 23:36:08

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:35:51', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'ad8c12e6-4987-42d6-90bd-2cf4182be6d2' User entered '100.9'	System	03 Sep 2020 23:36:08
	System	03 Sep 2020 23:36:08

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:35:55', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'ad8c12e6-4987-42d6-90bd-2cf4182be6d2' User entered 'No (N)'	System	03 Sep 2020 23:36:08
	System	03 Sep 2020 23:36:08

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:36:02', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'ad8c12e6-4987-42d6-90bd-2cf4182be6d2'	System	03 Sep 2020 23:36:08
User entered '03 Sep 2020 19:36'	System	03 Sep 2020 23:36:08

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	02 Sep 2020 18:35:19
User entered 'Day 3'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:40:24', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '1e7e0dfd-ca0e-40e4-bf10-857b7dede757'	System	04 Sep 2020 23:41:26
User entered 'Yes (Y)'	System	04 Sep 2020 23:41:26

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:41:09', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '1e7e0dfd-ca0e-40e4-bf10-857b7dede757' User entered '98.4'	System	04 Sep 2020 23:41:26
	System	04 Sep 2020 23:41:26

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:41:15', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '1e7e0dfd-ca0e-40e4-bf10-857b7dede757'	System	04 Sep 2020 23:41:26
User entered 'No (N)'	System	04 Sep 2020 23:41:26

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:41:22', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '1e7e0dfd-ca0e-40e4-bf10-857b7dede757' User entered '04 Sep 2020 19:41'	System	04 Sep 2020 23:41:26
	System	04 Sep 2020 23:41:26

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	02 Sep 2020 18:35:19
User entered 'Day 4'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:15:20', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '54d1b79b-2319-402d-9b5f-4440d7e2596b' User entered 'Yes (Y)'	System	06 Sep 2020 00:15:40
	System	06 Sep 2020 00:15:40

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:15:25', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '54d1b79b-2319-402d-9b5f-4440d7e2596b' User entered '97.0'	System	06 Sep 2020 00:15:40
	System	06 Sep 2020 00:15:40

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:15:30', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '54d1b79b-2319-402d-9b5f-4440d7e2596b'	System	06 Sep 2020 00:15:40
User entered 'No (N)'	System	06 Sep 2020 00:15:40

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:15:36', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '54d1b79b-2319-402d-9b5f-4440d7e2596b' User entered '05 Sep 2020 20:15'	System	06 Sep 2020 00:15:40
	System	06 Sep 2020 00:15:40

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	02 Sep 2020 18:35:19
User entered 'Day 5'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:16:17', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '355524b2-05c1-4179-9ff5-a11fa41439e0' User entered 'Yes (Y)'	System	07 Sep 2020 00:16:41
	System	07 Sep 2020 00:16:41

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:16:25', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '355524b2-05c1-4179-9ff5-a11fa41439e0' User entered '97.5'	System	07 Sep 2020 00:16:41
	System	07 Sep 2020 00:16:41

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:16:29', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '355524b2-05c1-4179-9ff5-a11fa41439e0' User entered 'No (N)'	System	07 Sep 2020 00:16:41
	System	07 Sep 2020 00:16:41

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:16:36', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '355524b2-05c1-4179-9ff5-a11fa41439e0' User entered '06 Sep 2020 20:16'	System	07 Sep 2020 00:16:41
	System	07 Sep 2020 00:16:41

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	02 Sep 2020 18:35:19
User entered 'Day 6'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:02:48', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'f47d9670-e4c2-4077-9292-e1bc4a5aa632' User entered 'Yes (Y)'	System	08 Sep 2020 00:03:08
	System	08 Sep 2020 00:03:08

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:02:57', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'f47d9670-e4c2-4077-9292-e1bc4a5aa632' User entered '98.1'	System	08 Sep 2020 00:03:08
	System	08 Sep 2020 00:03:08

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:01', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'f47d9670-e4c2-4077-9292-e1bc4a5aa632'	System	08 Sep 2020 00:03:08
User entered 'No (N)'	System	08 Sep 2020 00:03:08

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:04', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'f47d9670-e4c2-4077-9292-e1bc4a5aa632' User entered '07 Sep 2020 20:03'	System	08 Sep 2020 00:03:08
	System	08 Sep 2020 00:03:08

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	02 Sep 2020 18:35:19
User entered 'Day 7'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:34:51', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '217d420b-1d1a-4679-854a-d5ac8fc2ef0c' User entered 'Yes (Y)'	System	08 Sep 2020 23:35:15
	System	08 Sep 2020 23:35:15

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:34:59', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '217d420b-1d1a-4679-854a-d5ac8fc2ef0c' User entered '97.5'	System	08 Sep 2020 23:35:15
	System	08 Sep 2020 23:35:15

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:35:05', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '217d420b-1d1a-4679-854a-d5ac8fc2ef0c' User entered 'No (N)'	System	08 Sep 2020 23:35:15
	System	08 Sep 2020 23:35:15

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:35:10', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '217d420b-1d1a-4679-854a-d5ac8fc2ef0c' User entered '08 Sep 2020 19:35'	System	08 Sep 2020 23:35:15
	System	08 Sep 2020 23:35:15

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	02 Sep 2020 18:35:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:00:32', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'f4f9c2d5-48e4-4a5f-a402-066e2c8b072e' User entered 'None (1)'	System	02 Sep 2020 20:01:05
	System	02 Sep 2020 20:01:05

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:00:42', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'f4f9c2d5-48e4-4a5f-a402-066e2c8b072e' User entered 'No (N)'	System	02 Sep 2020 20:01:05
	System	02 Sep 2020 20:01:05

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:00:48', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'f4f9c2d5-48e4-4a5f-a402-066e2c8b072e' User entered 'No (N)'	System	02 Sep 2020 20:01:05
	System	02 Sep 2020 20:01:05

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:00:52', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'f4f9c2d5-48e4-4a5f-a402-066e2c8b072e' User entered 'None (1)'	System	02 Sep 2020 20:01:05
	System	02 Sep 2020 20:01:05

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:01:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'f4f9c2d5-48e4-4a5f-a402-066e2c8b072e' User entered '02 Sep 2020 16:01'	System	02 Sep 2020 20:01:05
	System	02 Sep 2020 20:01:05

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '02 Sep 2020 14:51'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '02 Sep 2020 17:21'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	02 Sep 2020 18:35:19
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:54:22', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e84add4a-2eb0-4fa0-ba0f-2afecf3fc7cd'	System	03 Sep 2020 00:55:14
User entered 'None (1)'	System	03 Sep 2020 00:55:14

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:54:26', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e84add4a-2eb0-4fa0-ba0f-2afecf3fc7cd' User entered 'No (N)'	System	03 Sep 2020 00:55:14
	System	03 Sep 2020 00:55:14

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:54:33', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e84add4a-2eb0-4fa0-ba0f-2afecf3fc7cd' User entered 'No (N)'	System	03 Sep 2020 00:55:14
	System	03 Sep 2020 00:55:14

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:54:39', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e84add4a-2eb0-4fa0-ba0f-2afecf3fc7cd' User entered 'None (1)'	System	03 Sep 2020 00:55:14
	System	03 Sep 2020 00:55:14

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:55:11', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e84add4a-2eb0-4fa0-ba0f-2afecf3fc7cd'	System	03 Sep 2020 00:55:14
User entered '02 Sep 2020 20:55'	System	03 Sep 2020 00:55:14

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '02 Sep 2020 18:16'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	02 Sep 2020 18:35:19
User entered 'Day 2'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:36:29', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '627ddce7-ee2c-426c-b9ee-af696d28660c'	System	03 Sep 2020 23:37:34
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 23:37:34

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:37:02', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '627ddce7-ee2c-426c-b9ee-af696d28660c' User entered 'No (N)'	System	03 Sep 2020 23:37:34
	System	03 Sep 2020 23:37:34

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:37:17', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '627ddce7-ee2c-426c-b9ee-af696d28660c' User entered 'No (N)'	System	03 Sep 2020 23:37:34
	System	03 Sep 2020 23:37:34

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:37:23', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '627ddce7-ee2c-426c-b9ee-af696d28660c' User entered 'None (1)'	System	03 Sep 2020 23:37:34
	System	03 Sep 2020 23:37:34

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:37:29', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '627ddce7-ee2c-426c-b9ee-af696d28660c' User entered '03 Sep 2020 19:37'	System	03 Sep 2020 23:37:34
	System	03 Sep 2020 23:37:34

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	02 Sep 2020 18:35:19
User entered 'Day 3'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:41:29', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '55b958c5-8516-414f-b25b-9c8a318d9fab'	System	04 Sep 2020 23:42:10
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 23:42:10

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:41:43', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '55b958c5-8516-414f-b25b-9c8a318d9fab' User entered 'No (N)'	System	04 Sep 2020 23:42:10
	System	04 Sep 2020 23:42:10

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:41:54', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '55b958c5-8516-414f-b25b-9c8a318d9fab' User entered 'No (N)'	System	04 Sep 2020 23:42:10
	System	04 Sep 2020 23:42:10

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:41:58', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '55b958c5-8516-414f-b25b-9c8a318d9fab'	System	04 Sep 2020 23:42:10
User entered 'None (1)'	System	04 Sep 2020 23:42:10

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:42:06', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '55b958c5-8516-414f-b25b-9c8a318d9fab' User entered '04 Sep 2020 19:42'	System	04 Sep 2020 23:42:10
	System	04 Sep 2020 23:42:10

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	02 Sep 2020 18:35:19
User entered 'Day 4'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:15:43', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2489d20b-a2be-4f93-96fa-962761e61e98' User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 00:16:16
	System	06 Sep 2020 00:16:16

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:15:52', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2489d20b-a2be-4f93-96fa-962761e61e98' User entered 'No (N)'	System	06 Sep 2020 00:16:16
	System	06 Sep 2020 00:16:16

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:15:58', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2489d20b-a2be-4f93-96fa-962761e61e98' User entered 'No (N)'	System	06 Sep 2020 00:16:16
	System	06 Sep 2020 00:16:16

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:16:04', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2489d20b-a2be-4f93-96fa-962761e61e98' User entered 'None (1)'	System	06 Sep 2020 00:16:16
	System	06 Sep 2020 00:16:16

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:16:14', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2489d20b-a2be-4f93-96fa-962761e61e98' User entered '05 Sep 2020 20:16'	System	06 Sep 2020 00:16:16
	System	06 Sep 2020 00:16:16

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	02 Sep 2020 18:35:19
User entered 'Day 5'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:16:52', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2e9f6a96-5c0b-4c4c-9ab9-0170e48b8a35' User entered 'None (1)'	System	07 Sep 2020 00:17:36
	System	07 Sep 2020 00:17:36

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:17:16', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2e9f6a96-5c0b-4c4c-9ab9-0170e48b8a35'	System	07 Sep 2020 00:17:36
User entered 'No (N)'	System	07 Sep 2020 00:17:36

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:17:21', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2e9f6a96-5c0b-4c4c-9ab9-0170e48b8a35'	System	07 Sep 2020 00:17:36
User entered 'No (N)'	System	07 Sep 2020 00:17:36

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:17:25', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2e9f6a96-5c0b-4c4c-9ab9-0170e48b8a35' User entered 'None (1)'	System	07 Sep 2020 00:17:36
	System	07 Sep 2020 00:17:36

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:17:30', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2e9f6a96-5c0b-4c4c-9ab9-0170e48b8a35' User entered '06 Sep 2020 20:17'	System	07 Sep 2020 00:17:36
	System	07 Sep 2020 00:17:36

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	02 Sep 2020 18:35:19
User entered 'Day 6'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:10', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0df3c28f-7003-4cdf-8153-a464a19ceeef' User entered 'None (1)'	System	08 Sep 2020 00:03:37
	System	08 Sep 2020 00:03:37

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:13', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0df3c28f-7003-4cdf-8153-a464a19ceef'	System	08 Sep 2020 00:03:37
User entered 'No (N)'	System	08 Sep 2020 00:03:37

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:22', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0df3c28f-7003-4cdf-8153-a464a19ceef' User entered 'No (N)'	System	08 Sep 2020 00:03:37
	System	08 Sep 2020 00:03:37

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:25', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0df3c28f-7003-4cdf-8153-a464a19ceef'	System	08 Sep 2020 00:03:37
User entered 'None (1)'	System	08 Sep 2020 00:03:37

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:28', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0df3c28f-7003-4cdf-8153-a464a19ceef'	System	08 Sep 2020 00:03:37
User entered '07 Sep 2020 20:03'	System	08 Sep 2020 00:03:37

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	02 Sep 2020 18:35:19
User entered 'Day 7'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:35:15', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '53d05e95-8ecc-4d17-a1cb-0b0ffca16da1' User entered 'None (1)'	System	08 Sep 2020 23:35:36
	System	08 Sep 2020 23:35:36

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:35:18', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '53d05e95-8ecc-4d17-a1cb-0b0ffca16da1' User entered 'No (N)'	System	08 Sep 2020 23:35:36
	System	08 Sep 2020 23:35:36

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:35:23', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '53d05e95-8ecc-4d17-a1cb-0b0ffca16da1' User entered 'No (N)'	System	08 Sep 2020 23:35:36
	System	08 Sep 2020 23:35:36

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:35:26', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '53d05e95-8ecc-4d17-a1cb-0b0ffca16da1' User entered 'None (1)'	System	08 Sep 2020 23:35:36
	System	08 Sep 2020 23:35:36

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:35:33', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '53d05e95-8ecc-4d17-a1cb-0b0ffca16da1' User entered '08 Sep 2020 19:35'	System	08 Sep 2020 23:35:36
	System	08 Sep 2020 23:35:36

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	02 Sep 2020 18:35:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:01:06', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '6c2bb8d1-a6d2-4601-9479-d06e473fe641' User entered 'None (0)'	System	02 Sep 2020 20:01:36
	System	02 Sep 2020 20:01:36

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:01:09', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '6c2bb8d1-a6d2-4601-9479-d06e473fe641' User entered 'None (0)'	System	02 Sep 2020 20:01:36
	System	02 Sep 2020 20:01:36

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:01:12', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '6c2bb8d1-a6d2-4601-9479-d06e473fe641' User entered 'None (0)'	System	02 Sep 2020 20:01:36
	System	02 Sep 2020 20:01:36

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:01:15', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '6c2bb8d1-a6d2-4601-9479-d06e473fe641' User entered 'None (0)'	System	02 Sep 2020 20:01:36
	System	02 Sep 2020 20:01:36

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:01:18', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '6c2bb8d1-a6d2-4601-9479-d06e473fe641' User entered 'None (0)'	System	02 Sep 2020 20:01:36
	System	02 Sep 2020 20:01:36

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:01:20', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '6c2bb8d1-a6d2-4601-9479-d06e473fe641' User entered 'None (0)'	System	02 Sep 2020 20:01:36
	System	02 Sep 2020 20:01:36

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:01:28', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '6c2bb8d1-a6d2-4601-9479-d06e473fe641' User entered 'No (N)'	System	02 Sep 2020 20:01:36
	System	02 Sep 2020 20:01:36

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T16:01:33', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '6c2bb8d1-a6d2-4601-9479-d06e473fe641' User entered '02 Sep 2020 16:01'	System	02 Sep 2020 20:01:36
	System	02 Sep 2020 20:01:36

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '02 Sep 2020 14:51'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '02 Sep 2020 17:21'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	02 Sep 2020 18:35:19
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:55:16', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '89005c5a-23bd-4aa0-b843-e1d2617d2f4d' User entered 'None (0)'	System	03 Sep 2020 00:55:52
	System	03 Sep 2020 00:55:52

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:55:21', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '89005c5a-23bd-4aa0-b843-e1d2617d2f4d' User entered 'None (0)'	System	03 Sep 2020 00:55:52
	System	03 Sep 2020 00:55:52

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:55:24', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '89005c5a-23bd-4aa0-b843-e1d2617d2f4d' User entered 'None (0)'	System	03 Sep 2020 00:55:52
	System	03 Sep 2020 00:55:52

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:55:27', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '89005c5a-23bd-4aa0-b843-e1d2617d2f4d' User entered 'None (0)'	System	03 Sep 2020 00:55:52
	System	03 Sep 2020 00:55:52

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:55:29', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '89005c5a-23bd-4aa0-b843-e1d2617d2f4d' User entered 'None (0)'	System	03 Sep 2020 00:55:52
	System	03 Sep 2020 00:55:52

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:55:31', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '89005c5a-23bd-4aa0-b843-e1d2617d2f4d' User entered 'None (0)'	System	03 Sep 2020 00:55:52
	System	03 Sep 2020 00:55:52

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:55:39', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '89005c5a-23bd-4aa0-b843-e1d2617d2f4d' User entered 'No (N)'	System	03 Sep 2020 00:55:52
	System	03 Sep 2020 00:55:52

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-02T20:55:47', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '89005c5a-23bd-4aa0-b843-e1d2617d2f4d' User entered '02 Sep 2020 20:55'	System	03 Sep 2020 00:55:52
	System	03 Sep 2020 00:55:52

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '02 Sep 2020 18:16'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	02 Sep 2020 18:35:19
User entered 'Day 2'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:37:37', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd7be2aac-56ef-48c8-84a3-50dd474e7a94'	System	03 Sep 2020 23:38:39
User entered 'No interference with activity (1)'	System	03 Sep 2020 23:38:39

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:37:43', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd7be2aac-56ef-48c8-84a3-50dd474e7a94'	System	03 Sep 2020 23:38:39
User entered 'Some interference with activity (2)'	System	03 Sep 2020 23:38:39

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:37:53', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd7be2aac-56ef-48c8-84a3-50dd474e7a94'	System	03 Sep 2020 23:38:39
User entered 'No interference with activity (1)'	System	03 Sep 2020 23:38:39

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:38:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd7be2aac-56ef-48c8-84a3-50dd474e7a94'	System	03 Sep 2020 23:38:39
User entered 'No interference with activity (1)'	System	03 Sep 2020 23:38:39

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:38:05', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd7be2aac-56ef-48c8-84a3-50dd474e7a94' User entered 'None (0)'	System	03 Sep 2020 23:38:39
	System	03 Sep 2020 23:38:39

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:38:19', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd7be2aac-56ef-48c8-84a3-50dd474e7a94'	System	03 Sep 2020 23:38:39
User entered 'Some interference with activity not requiring medical attention (2)'	System	03 Sep 2020 23:38:39

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:38:25', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd7be2aac-56ef-48c8-84a3-50dd474e7a94'	System	03 Sep 2020 23:38:39
User entered 'No (N)'	System	03 Sep 2020 23:38:39

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-03T19:38:34', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd7be2aac-56ef-48c8-84a3-50dd474e7a94' User entered '03 Sep 2020 19:38'	System	03 Sep 2020 23:38:39
	System	03 Sep 2020 23:38:39

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	02 Sep 2020 18:35:19
User entered 'Day 3'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:42:13', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '445fc2b7-51b2-44fe-bb6e-c3fa31e65829'	System	04 Sep 2020 23:43:14
User entered 'No interference with activity (1)'	System	04 Sep 2020 23:43:14

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:42:31', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '445fc2b7-51b2-44fe-bb6e-c3fa31e65829'	System	04 Sep 2020 23:43:14
User entered 'Some interference with activity (2)'	System	04 Sep 2020 23:43:14

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:42:36', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '445fc2b7-51b2-44fe-bb6e-c3fa31e65829'	System	04 Sep 2020 23:43:14
User entered 'No interference with activity (1)'	System	04 Sep 2020 23:43:14

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:42:42', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '445fc2b7-51b2-44fe-bb6e-c3fa31e65829'	System	04 Sep 2020 23:43:14
User entered 'No interference with activity (1)'	System	04 Sep 2020 23:43:14

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:42:46', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '445fc2b7-51b2-44fe-bb6e-c3fa31e65829' User entered 'None (0)'	System	04 Sep 2020 23:43:14
	System	04 Sep 2020 23:43:14

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:42:54', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '445fc2b7-51b2-44fe-bb6e-c3fa31e65829' User entered 'None (0)'	System	04 Sep 2020 23:43:14
	System	04 Sep 2020 23:43:14

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:42:58', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '445fc2b7-51b2-44fe-bb6e-c3fa31e65829' User entered 'No (N)'	System	04 Sep 2020 23:43:14
	System	04 Sep 2020 23:43:14

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-04T19:43:07', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '445fc2b7-51b2-44fe-bb6e-c3fa31e65829' User entered '04 Sep 2020 19:43'	System	04 Sep 2020 23:43:14
	System	04 Sep 2020 23:43:14

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	02 Sep 2020 18:35:19
User entered 'Day 4'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:16:19', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '063778cf-343b-4826-94d8-9f45b237afed' User entered 'None (0)'	System	06 Sep 2020 00:17:04
	System	06 Sep 2020 00:17:04

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:16:27', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '063778cf-343b-4826-94d8-9f45b237afed'	System	06 Sep 2020 00:17:04
User entered 'No interference with activity (1)'	System	06 Sep 2020 00:17:04

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:16:32', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '063778cf-343b-4826-94d8-9f45b237afed' User entered 'None (0)'	System	06 Sep 2020 00:17:04
	System	06 Sep 2020 00:17:04

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:16:37', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '063778cf-343b-4826-94d8-9f45b237afed' User entered 'None (0)'	System	06 Sep 2020 00:17:04
	System	06 Sep 2020 00:17:04

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:16:41', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '063778cf-343b-4826-94d8-9f45b237afed' User entered 'None (0)'	System	06 Sep 2020 00:17:04
	System	06 Sep 2020 00:17:04

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:16:44', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '063778cf-343b-4826-94d8-9f45b237afed' User entered 'None (0)'	System	06 Sep 2020 00:17:04
	System	06 Sep 2020 00:17:04

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:16:51', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '063778cf-343b-4826-94d8-9f45b237afed' User entered 'No (N)'	System	06 Sep 2020 00:17:04
	System	06 Sep 2020 00:17:04

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-05T20:16:58', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '063778cf-343b-4826-94d8-9f45b237afed' User entered '05 Sep 2020 20:16'	System	06 Sep 2020 00:17:04
	System	06 Sep 2020 00:17:04

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	02 Sep 2020 18:35:19
User entered 'Day 5'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:17:35', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'b0db1654-893e-40c2-af3d-1e480873ba0b' User entered 'None (0)'	System	07 Sep 2020 00:18:16
	System	07 Sep 2020 00:18:16

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:17:53', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'b0db1654-893e-40c2-af3d-1e480873ba0b' User entered 'No interference with activity (1)'	System	07 Sep 2020 00:18:16
	System	07 Sep 2020 00:18:16

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:17:56', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'b0db1654-893e-40c2-af3d-1e480873ba0b' User entered 'None (0)'	System	07 Sep 2020 00:18:16
	System	07 Sep 2020 00:18:16

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:17:59', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'b0db1654-893e-40c2-af3d-1e480873ba0b' User entered 'None (0)'	System	07 Sep 2020 00:18:16
	System	07 Sep 2020 00:18:16

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:18:01', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'b0db1654-893e-40c2-af3d-1e480873ba0b' User entered 'None (0)'	System	07 Sep 2020 00:18:16
	System	07 Sep 2020 00:18:16

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:18:03', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'b0db1654-893e-40c2-af3d-1e480873ba0b' User entered 'None (0)'	System	07 Sep 2020 00:18:16
	System	07 Sep 2020 00:18:16

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:18:08', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'b0db1654-893e-40c2-af3d-1e480873ba0b' User entered 'No (N)'	System	07 Sep 2020 00:18:16
	System	07 Sep 2020 00:18:16

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-06T20:18:11', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'b0db1654-893e-40c2-af3d-1e480873ba0b' User entered '06 Sep 2020 20:18'	System	07 Sep 2020 00:18:16
	System	07 Sep 2020 00:18:16

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	02 Sep 2020 18:35:19
User entered 'Day 6'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:32', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '94c8a7c5-6169-4223-a665-fc31d7dc7ce1' User entered 'None (0)'	System	08 Sep 2020 00:04:03
	System	08 Sep 2020 00:04:03

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:35', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '94c8a7c5-6169-4223-a665-fc31d7dc7ce1' User entered 'None (0)'	System	08 Sep 2020 00:04:03
	System	08 Sep 2020 00:04:03

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:39', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '94c8a7c5-6169-4223-a665-fc31d7dc7ce1' User entered 'None (0)'	System	08 Sep 2020 00:04:03
	System	08 Sep 2020 00:04:03

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:41', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '94c8a7c5-6169-4223-a665-fc31d7dc7ce1' User entered 'None (0)'	System	08 Sep 2020 00:04:03
	System	08 Sep 2020 00:04:03

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:43', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '94c8a7c5-6169-4223-a665-fc31d7dc7ce1' User entered 'None (0)'	System	08 Sep 2020 00:04:03
	System	08 Sep 2020 00:04:03

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:45', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '94c8a7c5-6169-4223-a665-fc31d7dc7ce1' User entered 'None (0)'	System	08 Sep 2020 00:04:03
	System	08 Sep 2020 00:04:03

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:49', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '94c8a7c5-6169-4223-a665-fc31d7dc7ce1' User entered 'No (N)'	System	08 Sep 2020 00:04:03
	System	08 Sep 2020 00:04:03

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-07T20:03:58', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '94c8a7c5-6169-4223-a665-fc31d7dc7ce1' User entered '07 Sep 2020 20:03'	System	08 Sep 2020 00:04:03
	System	08 Sep 2020 00:04:03

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	02 Sep 2020 18:35:19
User entered 'Day 7'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:35:38', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd44712b6-b1b0-4d87-ab55-693bb8813f27' User entered 'None (0)'	System	08 Sep 2020 23:36:11
	System	08 Sep 2020 23:36:11

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:35:40', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd44712b6-b1b0-4d87-ab55-693bb8813f27' User entered 'None (0)'	System	08 Sep 2020 23:36:11
	System	08 Sep 2020 23:36:11

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:35:44', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd44712b6-b1b0-4d87-ab55-693bb8813f27' User entered 'None (0)'	System	08 Sep 2020 23:36:11
	System	08 Sep 2020 23:36:11

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:35:48', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd44712b6-b1b0-4d87-ab55-693bb8813f27' User entered 'None (0)'	System	08 Sep 2020 23:36:11
	System	08 Sep 2020 23:36:11

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:35:50', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd44712b6-b1b0-4d87-ab55-693bb8813f27' User entered 'None (0)'	System	08 Sep 2020 23:36:11
	System	08 Sep 2020 23:36:11

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:35:53', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd44712b6-b1b0-4d87-ab55-693bb8813f27' User entered 'None (0)'	System	08 Sep 2020 23:36:11
	System	08 Sep 2020 23:36:11

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:36:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd44712b6-b1b0-4d87-ab55-693bb8813f27'	System	08 Sep 2020 23:36:11
User entered 'No (N)'	System	08 Sep 2020 23:36:11

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-09-08T19:36:06', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd44712b6-b1b0-4d87-ab55-693bb8813f27' User entered '08 Sep 2020 19:36'	System	08 Sep 2020 23:36:11
	System	08 Sep 2020 23:36:11

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 18:35:19

US3822043

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:51:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 18:35:19

US3822043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Krishna Shah (b) (4)	06 Oct 2020 20:25:46

US3822043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '11 Sep 2020'	Krishna Shah (b) (4)	06 Oct 2020 20:25:46

US3822043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Contact Made (CONTACT MADE)'	Krishna Shah (b) (4)	06 Oct 2020 20:25:46

US3822043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	Krishna Shah (b) (4)	06 Oct 2020 20:25:46

US3822043

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Krishna Shah (b) (4)	06 Oct 2020 20:25:54

US3822043

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'I'	System	06 Oct 2020 20:25:54

US3822043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Krishna Shah (b) (4)	06 Oct 2020 20:26:32

US3822043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '18 Sep 2020'	Krishna Shah (b) (4)	06 Oct 2020 20:26:32

US3822043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Contact Made (CONTACT MADE)'	Krishna Shah (b) (4)	06 Oct 2020 20:26:32

US3822043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	Krishna Shah (b) (4)	06 Oct 2020 20:26:32

US3822043

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Krishna Shah (b) (4)	06 Oct 2020 20:26:46

US3822043

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'I'	System	06 Oct 2020 20:26:46

US3822043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Krishna Shah (b) (4)	06 Oct 2020 20:27:06

US3822043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '25 Sep 2020'	Krishna Shah (b) (4)	06 Oct 2020 20:27:06

US3822043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Contact Made (CONTACT MADE)'	Krishna Shah (b) (4)	06 Oct 2020 20:27:06

US3822043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	Krishna Shah (b) (4)	06 Oct 2020 20:27:06

US3822043

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Krishna Shah (b) (4)	06 Oct 2020 20:27:21

US3822043

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'I'	System	06 Oct 2020 20:27:21

US3822043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:02:11
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Krishna Shah (b) (4)	06 Oct 2020 20:27:34

US3822043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:02:11
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '1 Oct 2020'	Krishna Shah (b) (4)	06 Oct 2020 20:27:34

US3822043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:02:11
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Clinic (Clinic)'	Krishna Shah (b) (4)	06 Oct 2020 20:27:34

US3822043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:02:11
User entered 'VISIT3'	System	06 Oct 2020 20:27:34

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:02:11
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Krishna Shah (b) (4)	06 Oct 2020 20:28:05

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:02:11
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '1 Oct 2020'	Krishna Shah (b) (4)	06 Oct 2020 20:28:05

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:02:11
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '13:20'	Krishna Shah (b) (4)	06 Oct 2020 20:28:05

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:02:11
User entered '1 Oct 2020 13:20'	System	06 Oct 2020 20:28:05

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:02:11
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '98.2' F	Krishna Shah (b) (4)	06 Oct 2020 20:28:05

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:02:11
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Oral (Oral)'	Krishna Shah (b) (4)	06 Oct 2020 20:28:05

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:02:11
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	Krishna Shah (b) (4)	06 Oct 2020 20:28:05

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:02:11
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '88'	Krishna Shah (b) (4)	06 Oct 2020 20:28:05

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:02:11
User entered 'bpm'	System	06 Oct 2020 20:28:05

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:02:11
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '20'	Krishna Shah (b) (4)	06 Oct 2020 20:28:05

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:02:11
User entered 'breaths/min'	System	06 Oct 2020 20:28:05

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:02:11
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '138'	Krishna Shah (b) (4)	06 Oct 2020 20:28:05

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:02:11
User entered 'mmHg'	System	06 Oct 2020 20:28:05

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:02:11
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '76'	Krishna Shah (b) (4)	06 Oct 2020 20:28:05

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:02:11
User entered 'mmHg'	System	06 Oct 2020 20:28:05

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:02:11

US3822043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:02:11

US3822043

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:02:11
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'No (N)'	Krishna Shah (b) (4)	06 Oct 2020 20:28:15

US3822043

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:02:11
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered empty.	Krishna Shah (b) (4)	06 Oct 2020 20:28:15

US3822043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:02:11
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Krishna Shah (b) (4)	06 Oct 2020 20:28:35

US3822043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:02:11
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '1 Oct 2020'	Krishna Shah (b) (4)	06 Oct 2020 20:28:35

US3822043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:52

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:02:11
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered '13:39'	Krishna Shah (b) (4)	06 Oct 2020 20:28:35

US3822043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:02:11
User entered '1 Oct 2020 13:39'	System	06 Oct 2020 20:28:35

US3822043

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:22:44
User entered 'Yes (Y)'	Krishna Shah (b) (4)	06 Oct 2020 20:28:41

US3822043

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'I'	System	06 Oct 2020 20:28:41

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 64'	System	07 Aug 2020 18:14:44

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-11T14:11:24', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0455e469-17bd-470b-b1f5-5ee48dd6378d' User entered 'Yes (Y)'	System	11 Oct 2020 18:12:16
	System	11 Oct 2020 18:12:16

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

Have you been exposed to someone with 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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-11T14:11:33', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0455e469-17bd-470b-b1f5-5ee48dd6378d' User entered 'No (N)'	System	11 Oct 2020 18:12:16
	System	11 Oct 2020 18:12:16

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-11T14:11:39', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0455e469-17bd-470b-b1f5-5ee48dd6378d' User entered 'No (N)'	System	11 Oct 2020 18:12:16
	System	11 Oct 2020 18:12:16

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-11T14:11:55', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0455e469-17bd-470b-b1f5-5ee48dd6378d' User entered 'No (N)'	System	11 Oct 2020 18:12:16
	System	11 Oct 2020 18:12:16

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-11T14:12:12', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0455e469-17bd-470b-b1f5-5ee48dd6378d' User entered '11 Oct 2020 14:12:12'	System	11 Oct 2020 18:12:16
	System	11 Oct 2020 18:12:16

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered '07 Oct 2020 00:01'	System	07 Aug 2020 18:14:44

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered '11 Oct 2020 23:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 71'	System	07 Aug 2020 18:14:44

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-14T00:02:22', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0818cd38-616f-453c-8d73-3d7d7e2cfdbe' User entered 'No (N)'	System	14 Oct 2020 04:02:43
	System	14 Oct 2020 04:02:43

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

Have you been exposed to someone with 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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-14T00:02:33', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0818cd38-616f-453c-8d73-3d7d7e2cfdbe'	System	14 Oct 2020 04:02:43
User entered 'No (N)'	System	14 Oct 2020 04:02:43

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-14T00:02:39', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '0818cd38-616f-453c-8d73-3d7d7e2cfdbe' User entered '14 Oct 2020 00:02:39'	System	14 Oct 2020 04:02:43
	System	14 Oct 2020 04:02:43

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered '14 Oct 2020 00:01'	System	07 Aug 2020 18:14:44

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered '18 Oct 2020 23:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 78'	System	07 Aug 2020 18:14:44

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-23T23:12:07', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2d18c8fe-e465-4db0-8d27-33adb568e777'	System	24 Oct 2020 03:12:47
User entered 'Yes (Y)'	System	24 Oct 2020 03:12:47

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

Have you been exposed to someone with 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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-23T23:11:13', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2d18c8fe-e465-4db0-8d27-33adb568e777'	System	24 Oct 2020 03:12:47
User entered 'No (N)'	System	24 Oct 2020 03:12:47

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-23T23:11:21', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2d18c8fe-e465-4db0-8d27-33adb568e777'	System	24 Oct 2020 03:12:47
User entered 'No (N)'	System	24 Oct 2020 03:12:47

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-23T23:11:30', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2d18c8fe-e465-4db0-8d27-33adb568e777'	System	24 Oct 2020 03:12:47
User entered 'Yes (Y)'	System	24 Oct 2020 03:12:47

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Please 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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-23T23:11:45', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2d18c8fe-e465-4db0-8d27-33adb568e777'	System	24 Oct 2020 03:12:47
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Oct 2020 03:12:47

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-10-23T23:12:23', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '2d18c8fe-e465-4db0-8d27-33adb568e777' User entered '23 Oct 2020 23:12:23'	System	24 Oct 2020 03:12:47
	System	24 Oct 2020 03:12:47

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered '21 Oct 2020 00:01'	System	07 Aug 2020 18:14:44

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered '25 Oct 2020 23:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 92'	System	07 Aug 2020 18:14:44

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-07T01:47:41', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'c3710cf0-5ce6-4e2a-98f3-db327a2e5a38'	System	07 Nov 2020 06:48:25
User entered 'No (N)'	System	07 Nov 2020 06:48:25

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

Have you been exposed to someone with 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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-07T01:47:57', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'c3710cf0-5ce6-4e2a-98f3-db327a2e5a38'	System	07 Nov 2020 06:48:25
User entered 'No (N)'	System	07 Nov 2020 06:48:25

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-07T01:48:21', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'c3710cf0-5ce6-4e2a-98f3-db327a2e5a38' User entered '07 Nov 2020 01:48:21'	System	07 Nov 2020 06:48:25
	System	07 Nov 2020 06:48:25

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered '04 Nov 2020 00:01'	System	07 Aug 2020 18:14:44

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered '08 Nov 2020 23:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 99'	System	07 Aug 2020 18:14:44

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-11T00:04:06', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '4057d283-1463-477c-bbb8-821009dc15c2'	System	11 Nov 2020 05:04:26
User entered 'No (N)'	System	11 Nov 2020 05:04:26

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

Have you been exposed to someone with 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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-11T00:04:15', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '4057d283-1463-477c-bbb8-821009dc15c2'	System	11 Nov 2020 05:04:26
User entered 'No (N)'	System	11 Nov 2020 05:04:26

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-11T00:04:20', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '4057d283-1463-477c-bbb8-821009dc15c2'	System	11 Nov 2020 05:04:26
User entered '11 Nov 2020 00:04:20'	System	11 Nov 2020 05:04:26

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered '11 Nov 2020 00:01'	System	07 Aug 2020 18:14:44

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered '15 Nov 2020 23:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered 'Day 106'	System	07 Aug 2020 18:14:44

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-18T00:01:49', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '9a9020ca-f944-4992-8ded-3ae777acfd2f' User entered 'No (N)'	System	18 Nov 2020 05:02:14
	System	18 Nov 2020 05:02:14

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

Have you been exposed to someone with 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 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-18T00:02:01', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '9a9020ca-f944-4992-8ded-3ae777acfd2f' User entered 'No (N)'	System	18 Nov 2020 05:02:14
	System	18 Nov 2020 05:02:14

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-18T00:02:07', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '9a9020ca-f944-4992-8ded-3ae777acfd2f' User entered '18 Nov 2020 00:02:07'	System	18 Nov 2020 05:02:14
	System	18 Nov 2020 05:02:14

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered '18 Nov 2020 00:01'	System	07 Aug 2020 18:14:44

US3822043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:43:40
Data entry locked.	System	07 Aug 2020 18:14:44
User entered '22 Nov 2020 23:59'	System	07 Aug 2020 18:14:44

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-19T21:58:29', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '850d0509-70fa-47bb-a6f9-4c5ee3e648ff' User entered 'No (N)'	System	20 Nov 2020 02:58:43

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

Have you been exposed to someone with 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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-19T21:58:33', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '850d0509-70fa-47bb-a6f9-4c5ee3e648ff' User entered 'No (N)'	System	20 Nov 2020 02:58:43

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-19T21:58:37', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '850d0509-70fa-47bb-a6f9-4c5ee3e648ff' User entered '19 Nov 2020 21:58:37'	System	20 Nov 2020 02:58:43

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-22T00:01:33', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '3aaeb1ad-b24e-4a11-8a00-9c7ad152dbfa' User entered 'No (N)'	System	22 Nov 2020 05:02:48
	System	22 Nov 2020 05:02:48

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

Have you been exposed to someone with 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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-22T00:01:40', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '3aaeb1ad-b24e-4a11-8a00-9c7ad152dbfa' User entered 'No (N)'	System	22 Nov 2020 05:02:48

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-22T00:01:50', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '3aaeb1ad-b24e-4a11-8a00-9c7ad152dbfa' User entered '22 Nov 2020 00:01:50'	System	22 Nov 2020 05:02:48
	System	22 Nov 2020 05:02:48

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-30T22:02:24', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '25ff76da-5f1d-4c19-9d46-311a03315261' User entered 'No (N)'	System	01 Dec 2020 03:02:46
	System	01 Dec 2020 03:02:46

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

Have you been exposed to someone with 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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-30T22:02:36', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '25ff76da-5f1d-4c19-9d46-311a03315261' User entered 'No (N)'	System	01 Dec 2020 03:02:46

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-11-30T22:02:41', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '25ff76da-5f1d-4c19-9d46-311a03315261' User entered '30 Nov 2020 22:02:41'	System	01 Dec 2020 03:02:46
	System	01 Dec 2020 03:02:46

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-12-06T22:55:48', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'c077dd88-a4a2-4805-bee8-a8de0ad36d69' User entered 'No (N)'	System	07 Dec 2020 03:57:28
	System	07 Dec 2020 03:57:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

Have you been exposed to someone with 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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-12-06T22:55:52', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'c077dd88-a4a2-4805-bee8-a8de0ad36d69' User entered 'No (N)'	System	07 Dec 2020 03:57:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-12-06T22:55:55', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'c077dd88-a4a2-4805-bee8-a8de0ad36d69' User entered '06 Dec 2020 22:55:55'	System	07 Dec 2020 03:57:28
	System	07 Dec 2020 03:57:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-12-13T00:02:12', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '89b7a698-b91f-42fa-8309-05629c900484' User entered 'No (N)'	System	13 Dec 2020 05:03:13
	System	13 Dec 2020 05:03:13

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Have you been exposed to someone with 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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-12-13T00:02:24', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '89b7a698-b91f-42fa-8309-05629c900484' User entered 'No (N)'	System	13 Dec 2020 05:03:13
	System	13 Dec 2020 05:03:13

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-12-13T00:02:45', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '89b7a698-b91f-42fa-8309-05629c900484' User entered '13 Dec 2020 00:02:45'	System	13 Dec 2020 05:03:13
	System	13 Dec 2020 05:03:13

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-12-20T23:25:59', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '430a68d4-785e-4be1-a20a-914a991667ec' User entered 'No (N)'	System	21 Dec 2020 04:26:16
	System	21 Dec 2020 04:26:16

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Have you been exposed to someone with 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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-12-20T23:26:05', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '430a68d4-785e-4be1-a20a-914a991667ec' User entered 'No (N)'	System	21 Dec 2020 04:26:16
	System	21 Dec 2020 04:26:16

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-12-20T23:26:13', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '430a68d4-785e-4be1-a20a-914a991667ec' User entered '20 Dec 2020 23:26:13'	System	21 Dec 2020 04:26:16
	System	21 Dec 2020 04:26:16

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-12-27T00:05:56', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'b5cce218-5a8b-48d0-b643-e4856ac4f90d' User entered 'No (N)'	System	27 Dec 2020 05:06:48
	System	27 Dec 2020 05:06:48

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

Have you been exposed to someone with 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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-12-27T00:06:01', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'b5cce218-5a8b-48d0-b643-e4856ac4f90d'	System	27 Dec 2020 05:06:48
User entered 'Yes (Y)'	System	27 Dec 2020 05:06:48

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Please 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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-12-27T00:06:17', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'b5cce218-5a8b-48d0-b643-e4856ac4f90d'	System	27 Dec 2020 05:06:48
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Dec 2020 05:06:48

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2020-12-27T00:06:35', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'b5cce218-5a8b-48d0-b643-e4856ac4f90d' User entered '27 Dec 2020 00:06:35'	System	27 Dec 2020 05:06:48
	System	27 Dec 2020 05:06:48

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-01-03T01:32:58', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '55ad324f-132a-4fa7-a270-82cc0f32a55a' User entered 'No (N)'	System	03 Jan 2021 06:33:19
	System	03 Jan 2021 06:33:19

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

Have you been exposed to someone with 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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-01-03T01:33:11', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '55ad324f-132a-4fa7-a270-82cc0f32a55a' User entered 'No (N)'	System	03 Jan 2021 06:33:19
	System	03 Jan 2021 06:33:19

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-01-03T01:33:15', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '55ad324f-132a-4fa7-a270-82cc0f32a55a' User entered '03 Jan 2021 01:33:15'	System	03 Jan 2021 06:33:19
	System	03 Jan 2021 06:33:19

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-01-10T00:06:24', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '821c2064-aa22-4e7c-9d6c-07115fa5873d' User entered 'No (N)'	System	10 Jan 2021 05:07:11
	System	10 Jan 2021 05:07:11

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Have you been exposed to someone with 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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-01-10T00:06:37', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '821c2064-aa22-4e7c-9d6c-07115fa5873d' User entered 'No (N)'	System	10 Jan 2021 05:07:11

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-01-10T00:07:08', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '821c2064-aa22-4e7c-9d6c-07115fa5873d' User entered '10 Jan 2021 00:07:08'	System	10 Jan 2021 05:07:11
	System	10 Jan 2021 05:07:11

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-01-17T08:59:21', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '6a90a3a6-dfeb-40b6-b901-c78f026e41d8'	System	17 Jan 2021 13:59:46
User entered 'No (N)'	System	17 Jan 2021 13:59:46

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Have you been exposed to someone with 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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-01-17T08:59:36', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '6a90a3a6-dfeb-40b6-b901-c78f026e41d8'	System	17 Jan 2021 13:59:46
User entered 'No (N)'	System	17 Jan 2021 13:59:46

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-01-17T08:59:42', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '6a90a3a6-dfeb-40b6-b901-c78f026e41d8' User entered '17 Jan 2021 08:59:42'	System	17 Jan 2021 13:59:46
	System	17 Jan 2021 13:59:46

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-01-24T00:43:59', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '37b6aebe-54e4-4e86-894a-c7a6476ec305'	System	24 Jan 2021 05:44:25
User entered 'No (N)'	System	24 Jan 2021 05:44:25

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Have you been exposed to someone with 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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-01-24T00:44:10', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '37b6aebc-54e4-4e86-894a-c7a6476ec305'	System	24 Jan 2021 05:44:25
User entered 'No (N)'	System	24 Jan 2021 05:44:25

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-01-24T00:44:23', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '37b6aebe-54e4-4e86-894a-c7a6476ec305' User entered '24 Jan 2021 00:44:23'	System	24 Jan 2021 05:44:25
	System	24 Jan 2021 05:44:25

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-01-31T00:29:48', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '20bd4c37-790a-4dcd-8f40-663a0ce715ff' User entered 'No (N)'	System	31 Jan 2021 05:30:09
	System	31 Jan 2021 05:30:09

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

Have you been exposed to someone with 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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-01-31T00:29:59', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '20bd4c37-790a-4dcd-8f40-663a0ce715ff' User entered 'No (N)'	System	31 Jan 2021 05:30:09

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-01-31T00:30:04', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '20bd4c37-790a-4dcd-8f40-663a0ce715ff' User entered '31 Jan 2021 00:30:04'	System	31 Jan 2021 05:30:09
	System	31 Jan 2021 05:30:09

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-02-07T23:02:52', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'f0b0f510-f4f3-44c9-acd2-1758363e9922'	System	08 Feb 2021 04:03:16
User entered 'No (N)'	System	08 Feb 2021 04:03:16

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Have you been exposed to someone with 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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-02-07T23:03:05', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'f0b0f510-f4f3-44c9-acd2-1758363e9922'	System	08 Feb 2021 04:03:16
User entered 'No (N)'	System	08 Feb 2021 04:03:16

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-02-07T23:03:10', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'f0b0f510-f4f3-44c9-acd2-1758363e9922'	System	08 Feb 2021 04:03:16
User entered '07 Feb 2021 23:03:10'	System	08 Feb 2021 04:03:16

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-02-14T00:02:09', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '7c2c2ed9-836a-4363-8c6b-18db2d5e4ba2' User entered 'No (N)'	System	14 Feb 2021 05:03:28
	System	14 Feb 2021 05:03:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Have you been exposed to someone with 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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-02-14T00:02:22', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '7c2c2ed9-836a-4363-8c6b-18db2d5e4ba2' User entered 'No (N)'	System	14 Feb 2021 05:03:28
	System	14 Feb 2021 05:03:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-02-14T00:02:30', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '7c2c2ed9-836a-4363-8c6b-18db2d5e4ba2' User entered '14 Feb 2021 00:02:30'	System	14 Feb 2021 05:03:28
	System	14 Feb 2021 05:03:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-02-21T00:01:33', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'dd261892-a43a-49eb-a909-45580f4e94b3' User entered 'No (N)'	System	21 Feb 2021 05:03:13
	System	21 Feb 2021 05:03:13

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

Have you been exposed to someone with 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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-02-21T00:01:42', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'dd261892-a43a-49eb-a909-45580f4e94b3' User entered 'No (N)'	System	21 Feb 2021 05:03:13
	System	21 Feb 2021 05:03:13

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-02-21T00:02:10', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'dd261892-a43a-49eb-a909-45580f4e94b3' User entered '21 Feb 2021 00:02:10'	System	21 Feb 2021 05:03:13
	System	21 Feb 2021 05:03:13

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-02-28T00:23:10-05:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '1cbea339-8d66-46dc-b11d-7353868cbf26' User entered 'No (N)'	System	28 Feb 2021 05:23:30
	System	28 Feb 2021 05:23:30

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

Have you been exposed to someone with 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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-02-28T00:23:17-05:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '1cbea339-8d66-46dc-b11d-7353868cbf26' User entered 'No (N)'	System	28 Feb 2021 05:23:30
	System	28 Feb 2021 05:23:30

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-02-28T00:23:23-05:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '1cbea339-8d66-46dc-b11d-7353868cbf26' User entered '28 Feb 2021 05:23:23'	System	28 Feb 2021 05:23:30
	System	28 Feb 2021 05:23:30

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-03-07T00:06:33-05:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '9afc3289-79b9-4adf-aba2-7f1ad1ab6efe' User entered 'No (N)'	System	07 Mar 2021 05:07:18
	System	07 Mar 2021 05:07:18

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

Have you been exposed to someone with 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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-03-07T00:06:52-05:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '9afc3289-79b9-4adf-aba2-7f1ad1ab6efe'	System	07 Mar 2021 05:07:18
User entered 'No (N)'	System	07 Mar 2021 05:07:18

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-03-07T00:06:59-05:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '9afc3289-79b9-4adf-aba2-7f1ad1ab6efe' User entered '07 Mar 2021 00:06:59'	System	07 Mar 2021 05:07:18
	System	07 Mar 2021 05:07:18

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-03-14T00:47:36-05:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e2071ce6-362b-4530-83cc-fbed182edc39'	System	14 Mar 2021 05:51:48
User entered 'No (N)'	System	14 Mar 2021 05:51:48

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Have you been exposed to someone with 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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-03-14T00:47:43-05:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e2071ce6-362b-4530-83cc-fbed182edc39'	System	14 Mar 2021 05:51:48
User entered 'No (N)'	System	14 Mar 2021 05:51:48

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-03-14T00:47:49-05:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e2071ce6-362b-4530-83cc-fbed182edc39' User entered '14 Mar 2021 00:47:49'	System	14 Mar 2021 05:51:48
	System	14 Mar 2021 05:51:48

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-03-23T21:06:51-04:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '790f49eb-ea93-4183-a27b-d5445b9a58bc' User entered 'No (N)'	System	24 Mar 2021 01:13:09
	System	24 Mar 2021 01:13:09

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Have you been exposed to someone with 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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-03-23T21:06:56-04:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '790f49eb-ea93-4183-a27b-d5445b9a58bc'	System	24 Mar 2021 01:13:09
User entered 'No (N)'	System	24 Mar 2021 01:13:09

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-03-23T21:07:00-04:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '790f49eb-ea93-4183-a27b-d5445b9a58bc' User entered '23 Mar 2021 21:07:00'	System	24 Mar 2021 01:13:09

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-03-28T00:03:19-04:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e70941b7-89ba-47e6-a580-5724c61de077'	System	28 Mar 2021 04:04:28
User entered 'No (N)'	System	28 Mar 2021 04:04:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

Have you been exposed to someone with 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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-03-28T00:03:32-04:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e70941b7-89ba-47e6-a580-5724c61de077'	System	28 Mar 2021 04:04:28
User entered 'No (N)'	System	28 Mar 2021 04:04:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-03-28T00:03:43-04:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'e70941b7-89ba-47e6-a580-5724c61de077'	System	28 Mar 2021 04:04:28
User entered '28 Mar 2021 00:03:43'	System	28 Mar 2021 04:04:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-04-04T00:02:41-04:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'ca5da07c-27c5-4f21-b47b-e64c1cbe5118'	System	04 Apr 2021 04:04:08
User entered 'No (N)'	System	04 Apr 2021 04:04:08

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

Have you been exposed to someone with 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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-04-04T00:02:57-04:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'ca5da07c-27c5-4f21-b47b-e64c1cbe5118'	System	04 Apr 2021 04:04:08
User entered 'No (N)'	System	04 Apr 2021 04:04:08

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-04-04T00:03:02-04:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'ca5da07c-27c5-4f21-b47b-e64c1cbe5118'	System	04 Apr 2021 04:04:08
User entered '04 Apr 2021 00:03:02'	System	04 Apr 2021 04:04:08

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-04-11T00:02:47-04:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '88440ffd-ee14-4e6d-a2cf-4b75022b9c25'	System	11 Apr 2021 04:04:16
User entered 'No (N)'	System	11 Apr 2021 04:04:16

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Have you been exposed to someone with 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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-04-11T00:02:59-04:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '88440ffd-ee14-4e6d-a2cf-4b75022b9c25'	System	11 Apr 2021 04:04:16
User entered 'No (N)'	System	11 Apr 2021 04:04:16

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-04-11T00:03:03-04:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '88440ffd-ee14-4e6d-a2cf-4b75022b9c25'	System	11 Apr 2021 04:04:16
User entered '11 Apr 2021 00:03:03'	System	11 Apr 2021 04:04:16

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-04-18T00:02:44-04:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd6a5d948-5a0f-482c-aa60-0f07f2010416'	System	18 Apr 2021 04:03:57
User entered 'No (N)'	System	18 Apr 2021 04:03:57

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

Have you been exposed to someone with 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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-04-18T00:02:53-04:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd6a5d948-5a0f-482c-aa60-0f07f2010416'	System	18 Apr 2021 04:03:57
User entered 'No (N)'	System	18 Apr 2021 04:03:57

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-04-18T00:02:58-04:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'd6a5d948-5a0f-482c-aa60-0f07f2010416'	System	18 Apr 2021 04:03:57
User entered '18 Apr 2021 00:02:58'	System	18 Apr 2021 04:03:57

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-04-25T22:25:04-04:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'f6122a57-24b0-4ba0-9dff-3a5cb744c8b5'	System	26 Apr 2021 02:25:19
User entered 'No (N)'	System	26 Apr 2021 02:25:19

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Have you been exposed to someone with 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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-04-25T22:25:10-04:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'f6122a57-24b0-4ba0-9dff-3a5cb744c8b5'	System	26 Apr 2021 02:25:19
User entered 'No (N)'	System	26 Apr 2021 02:25:19

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-04-25T22:25:14-04:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'f6122a57-24b0-4ba0-9dff-3a5cb744c8b5' User entered '25 Apr 2021 22:25:14'	System	26 Apr 2021 02:25:19
	System	26 Apr 2021 02:25:19

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-05-02T00:12:45-04:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '366088b6-891e-48fa-a7a8-68f529bb6669'	System	02 May 2021 04:13:02
User entered 'No (N)'	System	02 May 2021 04:13:02

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

Have you been exposed to someone with 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 (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-05-02T00:12:53-04:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '366088b6-891e-48fa-a7a8-68f529bb6669'	System	02 May 2021 04:13:02
User entered 'No (N)'	System	02 May 2021 04:13:02

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-05-02T00:12:59-04:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: '366088b6-891e-48fa-a7a8-68f529bb6669'	System	02 May 2021 04:13:02
User entered '02 May 2021 00:12:59'	System	02 May 2021 04:13:02

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 15:56:28

US3822043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:51:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:56:28
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 15:56:28

US3822043

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:51:52

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 18:21:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-02-28T00:26:43-05:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'afdf4357-f4f9-48a5-b2c1-1ccc0559f6fe'	System	28 Feb 2021 05:27:03
User entered 'No (N)'	System	28 Feb 2021 05:27:03

US3822043

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:51:52

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:21:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97183919-2F59-43F9-967D-722924A2497A)', Time: '2021-02-28T00:27:00-05:00', User OID: 'PatientReportedOutcome (US3822043)', ODM File OID: 'afdf4357-f4f9-48a5-b2c1-1ccc0559f6fe' User entered '28 Feb 2021 05:27:00'	System	28 Feb 2021 05:27:03
	System	28 Feb 2021 05:27:03

US3822043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:07:01
User entered 'Yes (Y)'	Krishna Shah (b) (4)	29 Oct 2020 19:49:40

US3822043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:07:01
User entered '29 Oct 2020'	Krishna Shah (b) (4)	29 Oct 2020 19:49:40

US3822043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:07:01
User entered 'Contact Made (CONTACT MADE)'	Krishna Shah (b) (4)	29 Oct 2020 19:49:40

US3822043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:07:01
User entered empty.	Krishna Shah (b) (4)	29 Oct 2020 19:49:40

US3822043

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:07:01
User entered 'Yes (Y)'	Krishna Shah (b) (4)	29 Oct 2020 19:49:45

US3822043

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:32
User entered 'I'	System	29 Oct 2020 19:49:45

US3822043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	11 Jan 2021 16:44:08

US3822043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered '1 Dec 2020'	Kelly Woodell (b) (4)	11 Jan 2021 16:44:08

US3822043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4)	11 Jan 2021 16:44:08

US3822043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered empty.	Kelly Woodell (b) (4)	11 Jan 2021 16:44:08

US3822043

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	11 Jan 2021 16:44:11

US3822043

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User entered 'I'	System	11 Jan 2021 16:44:11

US3822043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 20:53:34

US3822043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 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)	20 Jan 2021 18:29:12
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with '2 days out of window. deviation noted' (Site from System).	(b) (4), (b) (6)	14 Jan 2021 20:54:13
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	14 Jan 2021 20:53:34
User entered '5 Jan 2021'	(b) (4), (b) (6)	14 Jan 2021 20:53:34

US3822043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 20:53:34

US3822043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 20:53:34

US3822043

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 20:54:22

US3822043

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User entered 'I'	System	14 Jan 2021 20:54:22

US3822043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:32:34

US3822043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:32:34

US3822043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:32:34

US3822043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:32:34

US3822043

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:32:38

US3822043

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User entered 'I'	System	03 Feb 2021 21:32:38

US3822043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:24:56

US3822043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:24:56

US3822043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:52

[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 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:24:56

US3822043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:51:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User entered 'VISIT4'	System	26 Mar 2021 19:24:56

US3822043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:05:57

US3822043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:05:57

US3822043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:05:57

US3822043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User entered empty.	System	01 Apr 2021 15:05:57

US3822043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:05:57

US3822043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:05:57

US3822043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:05:57

US3822043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:05:57

US3822043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User entered empty.	System	01 Apr 2021 15:05:57

US3822043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:05:57

US3822043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User entered empty.	System	01 Apr 2021 15:05:57

US3822043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:05:57

US3822043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User entered empty.	System	01 Apr 2021 15:05:57

US3822043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:05:57

US3822043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User entered empty.	System	01 Apr 2021 15:05:57

US3822043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49

US3822043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:51:52

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49

US3822043

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:25:07

US3822043

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:51:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:25:07

US3822043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:25:18

US3822043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:25:18

US3822043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:52

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered '14:34'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:25:18

US3822043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User entered '02 Mar 2021 14:34'	System	26 Mar 2021 19:25:18

US3822043

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:25:23

US3822043

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:41:49
User entered 'I'	System	26 Mar 2021 19:25:23

US3822043

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:07
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:56:30

US3822043

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:07
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:56:30

US3822043

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:07
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:56:30

US3822043

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:51:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:07
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:56:30

US3822043

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:07
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:56:34

US3822043

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:51:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:00:07
User entered 'I'	System	30 Mar 2021 14:56:34

US3822043

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

Form: Visit Date

Generated On: 10 Jun 2021 09:51:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:37
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:35:28

US3822043

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

Form: Visit Date

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:37
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:35:28

US3822043

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

Form: Visit Date

Generated On: 10 Jun 2021 09:51:52

[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 23:15:37
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:35:28

US3822043

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

Form: Visit Date

Generated On: 10 Jun 2021 09:51:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:37
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 21:35:28

US3822043

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

Form: Unblinding

Generated On: 10 Jun 2021 09:51:52

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:37
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:35:40

US3822043

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

Form: Unblinding

Generated On: 10 Jun 2021 09:51:52

[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 23:15:37
User signature succeeded.	Christina Kennelly (b) (4)	11 Apr 2021 23:57:12
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:03:02
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:25:13

US3822043

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

Form: Unblinding

Generated On: 10 Jun 2021 09:51:52

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:37
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:35:40

US3822043

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

Form: Unblinding

Generated On: 10 Jun 2021 09:51:52

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:37
User closed query 'Per CDM: Per Sponsor review: 'Under what version of the Protocol was the participant unblinded?' is blank - Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 03:52:48
User signature succeeded.	Christina Kennelly (b) (4)	11 Apr 2021 23:57:12
Query 'Per CDM: Per Sponsor review: 'Under what version of the Protocol was the participant unblinded?' is blank - Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. Thank you. ' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:03:58
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	08 Apr 2021 15:03:02
User opened query 'Per CDM: Per Sponsor review: 'Under what version of the Protocol was the participant unblinded?' is blank - Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 10:44:18
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:25:13

US3822043

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

Form: Unblinding

Generated On: 10 Jun 2021 09:51:52

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:37
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Apr 2021 14:35:45
User closed query 'Per CDM : Per IRT : subject was unblinded on 19JAN2021. Please review and reconcile. Thank You' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 14:35:40
User signature succeeded.	Christina Kennelly (b) (4)	11 Apr 2021 23:57:12
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'Date is correct as is' (Site from System).	Kelly Woodell (b) (4)	08 Apr 2021 15:07:16
Query 'Per CDM : Per IRT : subject was unblinded on 19JAN2021. Please review and reconcile. Thank You' answered with 'Date updated' (Site from DM).	Kelly Woodell (b) (4)	08 Apr 2021 15:06:08
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	08 Apr 2021 15:05:51
Signature has been broken.	Kelly Woodell (b) (4)	08 Apr 2021 15:05:51
User entered '19 Jan 2021' reason for change: Data Entry Error	Kelly Woodell (b) (4)	08 Apr 2021 15:05:51
User opened query 'Per CDM : Per IRT : subject was unblinded on 19JAN2021. Please review and reconcile. Thank You' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:50:43
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered '20 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 21:35:40

US3822043

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

Form: Unblinding

Generated On: 10 Jun 2021 09:51:52

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:37
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:35:40

US3822043

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

Form: Unblinding

Generated On: 10 Jun 2021 09:51:52

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:37
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:35:40

US3822043

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

Form: Unblinding

Generated On: 10 Jun 2021 09:51:52

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:37
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:35:40

US3822043

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

Form: Unblinding

Generated On: 10 Jun 2021 09:51:52

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:37
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:35:40

US3822043

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

Form: Unblinding

Generated On: 10 Jun 2021 09:51:52

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:37
User entered empty.	System	20 Jan 2021 21:35:40

US3822043

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

Form: Unblinding

Generated On: 10 Jun 2021 09:51:52

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:37
User entered empty.	System	20 Jan 2021 21:35:40

US3822043

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:37
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:36:02

US3822043

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:37
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:36:02

US3822043

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:52

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:37
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered '13:26'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:36:02

US3822043

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:51:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:37
User entered '20 Jan 2021 13:26'	System	20 Jan 2021 21:36:02

US3822043

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:51:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:37
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:36:17

US3822043

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:37
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:36:17

US3822043

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:51:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:37
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered '13:35'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:36:17

US3822043

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:51:52

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:15:37
User entered '20 Jan 2021 13:35'	System	20 Jan 2021 21:36:17

US3822043

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:51:52

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:13:53
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
User closed query 'Please confirm Yes, as Adverse Events are included in EDC.' (Site from CRA).	(b) (4)	19 Nov 2020 13:50:16
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 13:50:10
Query 'Please confirm Yes, as Adverse Events are included in EDC.' answered with 'updated' (Site from CRA).	Krishna Shah (b) (4)	18 Nov 2020 21:26:10
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 21:26:04
User opened query 'Please confirm Yes, as Adverse Events are included in EDC.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 19:57:20
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 19:56:37
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:56:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 15:08:00
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	26 Aug 2020 02:07:33

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4)	18 Nov 2020 14:43:21
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:56:33
User entered	System	26 Oct 2020 20:56:27
'USA-US126-2020-mRNA-1273-P301000006'		
User entered 'New'	(b) (4), (b) (6)	26 Oct 2020 20:56:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
User closed query 'PV Query: Onset date of event has been updated to 02 Oct 2020. Please consider removing medical history of small lymphocytic lymphoma.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:46:01
User closed query 'Per DM CLR: Please note that this medical condition is also recorded in the Medical History eCRF. Review and ensure that there is no duplicate entry and this is recorded in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 09:45:58
Query 'PV Query: Onset date of event has been updated to 02 Oct 2020. Please consider removing medical history of small lymphocytic lymphoma.' answered with 'REMOVED' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 18:41:08
Query 'Per DM CLR: Please note that this medical condition is also recorded in the Medical History eCRF. Review and ensure that there is no duplicate entry and this is recorded in the appropriate eCRF. ' answered with 'UPDATED. MED HX WAS INACTIVATED' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 18:41:00
User opened query 'PV Query: Onset date of event has been updated to 02 Oct 2020. Please consider removing medical history of small lymphocytic lymphoma.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 15:38:12
User opened query 'Per DM CLR: Please note that this medical condition is also recorded in the Medical History eCRF. Review and ensure that there is no duplicate entry and this is recorded in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 01:47:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 14:43:23
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Lymphomas non-Hodgkin's B-cell, HLT: B-cell small lymphocytic lymphomas, PT: B-cell small lymphocytic lymphoma, LLT: Small cell lymphocytic lymphoma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:46:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:46:40
Data point term sent to Coder	System	23 Oct 2020 17:37:29

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Small Lymphocytic lymphoma'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:43:25
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:43:27
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:43:29
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 15:55:37
User closed query 'PV Query: Please assess the start date of the event 06 Oct 2020. The biopsy performed on 02 Oct 2020 revealed partial involvement by small lymphocytic lymphoma/chronic lymphocytic leukemia. If the start date is to remain as 06 Oct 2020, please explain. ' (Site from Safety).	(b) (4), (b) (6)	15 Jan 2021 17:10:32
Query 'PV Query: Please assess the start date of the event 06 Oct 2020. The biopsy performed on 02 Oct 2020 revealed partial involvement by small lymphocytic lymphoma/chronic lymphocytic leukemia. If the start date is to remain as 06 Oct 2020, please explain. ' answered with 'updated' (Site from Safety).	Kelly Woodell (b) (4)	14 Jan 2021 17:02:34
	(b) (4)	
DataPoint Un-verified.	Kelly Woodell (b) (4)	14 Jan 2021 17:02:26
	(b) (4)	
User entered '02 Oct 2020' reason for change: Data Entry Error	Kelly Woodell (b) (4)	14 Jan 2021 17:02:26
	(b) (4)	
User opened query 'PV Query: Please assess the start date of the event 06 Oct 2020. The biopsy performed on 02 Oct 2020 revealed partial involvement by small lymphocytic lymphoma/chronic lymphocytic leukemia. If the start date is to remain as 06 Oct 2020, please explain. ' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 14:49:40
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 14:43:33
User entered '06 Oct 2020'	Kelly Woodell (b) (4)	23 Oct 2020 17:37:27
	(b) (4)	

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:25:11
User closed query 'Please enter data into EDC if applicable.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:50:45
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:50:42
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'Keep getting asked to provide time and remove time. Which do I do?' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 13:48:18
Query 'Please enter data into EDC if applicable.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 13:47:33
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	23 Nov 2020 13:47:25
User entered '11:00' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:47:25
User opened query 'Please enter data into EDC if applicable.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 13:48:56
User closed query 'Per CRIO source, 11:00 is noted. Please reconcile and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 13:48:56
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	18 Nov 2020 21:16:43
User entered empty; reason for change Data Entry Error	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:16:43
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'Time was entered per previous query. Time is removed again.' (Site from System).	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:16:22
Query 'Per CRIO source, 11:00 is noted. Please reconcile and update if applicable.' answered with 'updated' (Site from CRA).	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:15:42
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	18 Nov 2020 21:15:30

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:00' reason for change: Data Entry Error	Krishna Shah (b) (4)	18 Nov 2020 21:15:30
User opened query 'Per CRIO source, 11:00 is noted. Please reconcile and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 14:44:10
User entered empty.	Kelly Woodell (b) (4)	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:00'	System	14 Jan 2021 17:02:26
User entered '06 Oct 2020 11:00'	System	23 Nov 2020 13:47:25
User entered empty.	System	18 Nov 2020 21:16:43
User entered '06 Oct 2020 11:00'	System	18 Nov 2020 21:15:30
User entered empty.	System	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:55:42
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	22 Dec 2020 14:48:03
DataPoint Un-verified.	Krishna Shah (b) (4)	22 Dec 2020 14:48:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Krishna Shah (b) (4)	22 Dec 2020 14:48:03
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	22 Dec 2020 14:47:48
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 14:44:16
User entered 'Yes (Y)'	(b) (4) Kelly Woodell (b) (4)	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 15:55:45
User closed query 'PV Query: If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 20:28:48
Query 'PV Query: If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' answered with 'New baseline established, see comment section below. ' (Site from Safety).	Krishna Shah (b) (4)	22 Dec 2020 14:48:29
	(b) (4)	
DataPoint Un-verified.	Krishna Shah (b) (4)	22 Dec 2020 14:47:48
	(b) (4)	
User entered '22 Dec 2020' reason for change: Data Entry Error	Krishna Shah (b) (4)	22 Dec 2020 14:47:48
	(b) (4)	
User opened query 'PV Query: If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 15:33:46
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:28:15
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'not yet recovered' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 13:48:28
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 14:44:30

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 23:27:25
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 15:38:51
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Subject has not followed up with oncology since 10/21/2020. At this time no treatment has been given therefore SAE is still ongoing.' (Site from Safety).	Kelly Woodell (b) (4)	04 Nov 2020 15:38:32
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 18:01:37
User entered empty.	Kelly Woodell (b) (4)	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:44:34
User entered empty.	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:44:37
User entered 'Grade 3/Severe (Grade 3/Severe)'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:44:39
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:45:10
User entered '0'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:45:12
User entered '0'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:45:13
User entered '0'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:45:15
User entered empty.	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:45:17
User entered empty.	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:45:21
User entered empty.	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:45:22
User entered empty.	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:45:24
User entered '0'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:45:33
User entered '0'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:45:36
User entered 'I'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:45:37
	(b) (4), (b) (6)	06 Nov 2020 15:38:54
User closed query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug.' (Site from Safety).		
Query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug.' answered with 'PI rationale is that the even was diagnosed a month after 2nd injection' (Site from Safety).	Kelly Woodell (b) (4)	04 Nov 2020 15:49:05
	(b) (4)	
User opened query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 18:00:43
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 12:31:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 12:31:16
User entered 'Related (RELATED)' reason for change: Data Entry Error	Kelly Woodell (b) (4)	27 Oct 2020 12:31:16
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 17:37:27
User entered empty.	Kelly Woodell (b) (4)	23 Oct 2020 17:37:27
	(b) (4)	

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:50:14
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.	(b) (4), (b) (6)	19 Nov 2020 15:10:59
' (Site from DM).		
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.	Krishna Shah (b) (4)	18 Nov 2020 21:23:18
' answered with 'updated ' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Krishna Shah (b) (4)	18 Nov 2020 21:23:05
	(b) (4)	
User entered 'Related (RELATED)' reason for change: Data Entry Error	Krishna Shah (b) (4)	18 Nov 2020 21:23:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:45:42
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.	(b) (4), (b) (6)	18 Nov 2020 08:04:04
' (Site from DM).		
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 12:31:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 12:31:16
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Kelly Woodell (b) (4)	27 Oct 2020 12:31:16
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 17:37:27
User entered empty.	Kelly Woodell (b) (4)	23 Oct 2020 17:37:27
	(b) (4)	

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:45:46
User entered 'Not Applicable (NOT APPLICABLE)'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

None

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
User closed query 'Per DM CLR: Please review if there are treatments given for this Serious AE, as treatment is expected. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:38:47
Query 'Per DM CLR: Please review if there are treatments given for this Serious AE, as treatment is expected. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' answered with 'There is no treatment being given currently. See comments section below. ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	22 Dec 2020 14:48:51
User opened query 'Per DM CLR: Please review if there are treatments given for this Serious AE, as treatment is expected. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 00:37:53
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 14:45:50
User entered 'I'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:45:52
User entered '0'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:45:55
User entered '0'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 13:28:54
User closed query 'PV Query: Please provide the final event outcome, when available. ' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 20:28:53
Query 'PV Query: Please provide the final event outcome, when available. ' answered with 'updated ' (Site from Safety).	Krishna Shah (b) (4)	22 Dec 2020 14:49:00
DataPoint Un-verified.	(b) (4)	
	Krishna Shah (b) (4)	22 Dec 2020 14:47:48
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Krishna Shah (b) (4)	22 Dec 2020 14:47:48
reason for change: 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)	03 Dec 2020 15:36:08
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:28:26
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'This is not expected to have a resolution date in the near future. ' (Site from Safety).	Krishna Shah (b) (4)	23 Nov 2020 17:39:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:45:57
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 23:25:59
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 15:38:56

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Outcome is correct as is' (Site from Safety).	Kelly Woodell (b) (4) (b) (4)	04 Nov 2020 15:47:53
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 18:00:04
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

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 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 13:28:58
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	22 Dec 2020 14:50:19
DataPoint Un-verified.	Krishna Shah (b) (4)	22 Dec 2020 14:50:19
User entered 'Per MD, the patient has stable disease at this time and is being watched for progression. the patient does not currently meet criteria to start first line treatment.' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	22 Dec 2020 14:50:19
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	22 Dec 2020 14:47:48
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 14:46:02
User entered empty.	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
User closed query 'PV Query: We did not receive the oncology consultation notes. Please send again with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:25:50
Query 'PV Query: We did not receive the oncology consultation notes. Please send again with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Record were sent to safety on 27JAN2021 at 09:06 ' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 14:06:43
User opened query 'PV Query: We did not receive the oncology consultation notes. Please send again with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 15:36:50
User closed query 'PV Query: Please provide oncology consultation notes when available with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	15 Jan 2021 17:10:26
Query 'PV Query: Please provide oncology consultation notes when available with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'These were emailed to safety on 11/4/2020' (Site from Safety).	Kelly Woodell (b) (4) (b) (4)	14 Jan 2021 17:03:09

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide oncology consultation notes when available with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 13:05:48
User closed query 'PV Query: Please provide oncology consultation notes when available with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 16:44:29
Query 'PV Query: Please provide oncology consultation notes when available with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Available medical records emailed.' (Site from Safety).	Krishna Shah (b) (4) (b) (4)	29 Dec 2020 23:47:53
User opened query 'PV Query: Please provide oncology consultation notes when available with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 19:13:58
User closed query 'PV Query: Please provide oncology consultation notes when available with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 20:28:58

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide oncology consultation notes when available with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'no medical records available at this time. ' (Site from Safety).	Krishna Shah (b) (4) (b) (4)	22 Dec 2020 14:50:38
User opened query 'PV Query: Please provide oncology consultation notes when available with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	03 Dec 2020 15:38:16
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments (or plan for treatment). 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) (b) (4)	24 Nov 2020 19:28:30
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments (or plan for treatment). 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.' answered with 'No treatment was provided' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6) (b) (4)	23 Nov 2020 15:29:30
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments (or plan for treatment). 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) (b) (4), (b) (6) (b) (4)	18 Nov 2020 14:46:25 13 Nov 2020 23:26:38

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please report if the patient has any risk factors for small cell lymphocytic lymphoma.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 15:39:04
User closed query 'PV Query: Has the subject seen an oncologist or have a future appointment scheduled?' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 15:39:03
User closed query 'PV Query: Please provide the date of biopsy.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 15:39:02
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments (or plan for treatment). 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 15:39:00
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test (i.e. additional scans) results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 15:38:58
Query 'PV Query: Please provide any relevant laboratory and diagnostic test (i.e. additional scans) results. Please include units and reference ranges if applicable.' answered with 'All diagnostic test have been added to the concomitant procedure page' (Site from Safety).	Kelly Woodell (b) (4)	04 Nov 2020 15:50:54
Query 'PV Query: Please report if the patient has any risk factors for small cell lymphocytic lymphoma.' answered with 'There were no risk factors known' (Site from Safety).	Kelly Woodell (b) (4)	04 Nov 2020 15:50:31
Query 'PV Query: Has the subject seen an oncologist or have a future appointment scheduled?' answered with 'The subject has seen an oncologist. Records will be submitted today to safety.' (Site from Safety).	Kelly Woodell (b) (4)	04 Nov 2020 15:50:09
Query 'PV Query: Please provide the date of biopsy.' answered with 'Biopsy date is recorded on concomitant procedures page' (Site from Safety).	Kelly Woodell (b) (4)	04 Nov 2020 15:49:49

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments (or plan for treatment). 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.' answered with 'No treatment or plan have been given' (Site from Safety).	Kelly Woodell (b) (4)	04 Nov 2020 15:48:14
User opened query 'PV Query: Please report if the patient has any risk factors for small cell lymphocytic lymphoma.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 18:02:43
User opened query 'PV Query: Has the subject seen an oncologist or have a future appointment scheduled?' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 18:02:27
User opened query 'PV Query: Please provide the date of biopsy.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 18:02:09
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments (or plan for treatment). 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)	02 Nov 2020 18:00:22
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test (i.e. additional scans) results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 17:59:19
User entered 'The patient was scheduled for routine CT of the chest to screen for lung cancer on 9/5/2020. The CT showed an enlarged let axillary lymph node that was new since 6/26/2018. Due to the findings the subject was scheduled for an ultrasound guided biopsy. The biopsy results were small lymphocytic lymphoma.'	Kelly Woodell (b) (4)	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:51:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 17:37:27

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User closed query 'Per DM CLR: Please review if this AE is considered as Lymphadenopathy. If yes, please update to record Lymphadenopathy and update to specify its location and indicate whether this is Ipsilateral or Contralateral to Injection Site. Please update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 10:03:06
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 13:58:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 13:58:56
Data point term sent to Coder	System	16 Mar 2021 13:58:07
Query 'Per DM CLR: Please review if this AE is considered as Lymphadenopathy. If yes, please update to record Lymphadenopathy and update to specify its location and indicate whether this is Ipsilateral or Contralateral to Injection Site. Please update applicable details as appropriate. Otherwise, clarify.' answered with 'Term updated' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	16 Mar 2021 13:57:39
DataPoint Un-verified.	Kelly Woodell (b) (4) (b) (4)	16 Mar 2021 13:57:29
Coding entries removed.	Kelly Woodell (b) (4) (b) (4)	16 Mar 2021 13:57:29
Signature has been broken.	Kelly Woodell (b) (4) (b) (4)	16 Mar 2021 13:57:29
User entered 'IPSILATERAL Lymphadenopathy' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	16 Mar 2021 13:57:29

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if this AE is considered as Lymphadenopathy. If yes, please update to record Lymphadenopathy and update to specify its location and indicate whether this is Ipsilateral or Contralateral to Injection Site. Please update applicable details as appropriate. Otherwise, clarify.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Christina Kennelly (b) (4)	13 Mar 2021 17:17:27 12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:01:28
User closed query 'Per CDM: "To help clarify the clinical significance of the event (Injection site ...)an possible association with the administration of investigational product and/or study procedure, if this event is related to the site of administration, please update the Adverse Event to "Injection site (discomfort, pain, swelling, nodule, mass, irritation, bruising, rash, dermatitis)." (Site from DM). User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy axillary - version MedDRA\23.0.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	19 Feb 2021 06:35:09 17 Feb 2021 10:56:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 10:56:02
Data point term sent to Coder	System	12 Feb 2021 16:16:06
Query 'Per CDM: "To help clarify the clinical significance of the event (Injection site ...)and possible association with the administration of investigational product and/or study procedure, if this event is related to the site of administration, please update the Adverse Event to "Injection site (discomfort, pain, swelling, nodule, mass, irritation, bruising, rash, dermatitis)." answered with 'UPDATED' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Feb 2021 16:15:52 12 Feb 2021 16:15:46
Coding entries removed.	(b) (4), (b) (6)	12 Feb 2021 16:15:46

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'ENLARGED IPSILATERAL AXILLARY LYMPH NODES NOT RELATED TO VACCINE' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Feb 2021 16:15:46
User opened query 'Per CDM: "To help clarify the clinical significance of the event (Injection site ...)an possible association with the administration of investigational product and/or study procedure, if this event is related to the site of administration, please update the Adverse Event to "Injection site (discomfort, pain, swelling, nodule, mass, irritation, bruising, rash, dermatitis)." (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 01:42:44
User closed query 'Per CDM (CLR Re-Query): Site response noted; however, please also include "ipsilateral" in the AE term. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 14:52:37
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy axillary - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Jan 2021 09:43:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Jan 2021 16:15:04
Data point term sent to Coder	System	27 Jan 2021 16:15:04
Query 'Per CDM (CLR Re-Query): Site response noted; however, please also include "ipsilateral" in the AE term. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 14:08:58
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 14:08:19
Coding entries removed.	(b) (4), (b) (6)	27 Jan 2021 14:08:13
User entered 'ENLARGED ipsilateral AXILLARY LYMPH NODES' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 14:08:13
User opened query 'Per CDM (CLR Re-Query): Site response noted; however, please also include "ipsilateral" in the AE term. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 09:59:26

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 09:59:26
Query 'Per DM CLR: Please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. ' answered with 'Noted left which is the same side as vaccine' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 18:42:55
User opened query 'Per DM CLR: Please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 01:48:19
User closed query 'Per DM CLR: Please review if this AE is considered as Lymphadenopathy. If yes, please update to record Lymphadenopathy and specify the location (e.g. Axillary, etc.) and indicate whether this is Ipsilateral or Contralateral to Injection Site. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 07:16:04
Query 'Per DM CLR: Please review if this AE is considered as Lymphadenopathy. If yes, please update to record Lymphadenopathy and specify the location (e.g. Axillary, etc.) and indicate whether this is Ipsilateral or Contralateral to Injection Site. Please review and update applicable details as appropriate. Otherwise, clarify.' answered with 'Please see this developed into Small lymphocytic lymphoma, see AE entered. ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	21 Dec 2020 21:49:30
User coded data point as SOC: Blood and lymphatic system disorders, HLG: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy axillary - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Dec 2020 17:36:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Dec 2020 17:36:00

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if this AE is considered as Lymphadenopathy. If yes, please update to record Lymphadenopathy and specify the location (e.g. Axillary, etc.) and indicate whether this is Ipsilateral or Contralateral to Injection Site. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 00:37:17
	(b) (4), (b) (6)	18 Nov 2020 14:46:53
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Axillary lymph nodes enlarged - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 22:42:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 22:42:37
Data point term sent to Coder	System	23 Oct 2020 17:42:53
User entered 'Enlarged left axillary lymph nodes'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:46:57
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:46:59
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:47:01
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:47:04
User entered '5 Sep 2020'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:51
User closed query 'Please re-review CRIO ad update Start Time if applicable. Data entry time is 15:29 vs. AE start time is noted as 13:06. Please reconcile and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:51:49
Query 'Please re-review CRIO ad update Start Time if applicable. Data entry time is 15:29 vs. AE start time is noted as 13:06. Please reconcile and update if applicable.' answered with 'START TIME IS NOT REQUIRED SINCE IT DID NOT START WITHIN 24 HOURS OF IP' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 14:10:44
User closed query 'Start time is present for an AE that System did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).		23 Nov 2020 14:10:35
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 14:10:35
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	23 Nov 2020 14:09:49
User entered '13:06' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 14:09:49
User opened query 'Please re-review CRIO ad update Start Time if applicable. Data entry time is 15:29 vs. AE start time is noted as 13:06. Please reconcile and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:48:40
User closed query 'Per CRIO source, start time is 13:06. Please reconcile and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:48:40
Query 'Per CRIO source, start time is 13:06. Please reconcile and update if applicable.' answered with 'That was the time of data entry not a start time. Time unknown.' (Site from CRA).	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:24:24
User opened query 'Per CRIO source, start time is 13:06. Please reconcile and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 14:47:38
User entered empty.	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User entered empty.	System	23 Nov 2020 14:10:35
User entered '5 Sep 2020 13:06'	System	23 Nov 2020 14:09:49
User entered empty.	System	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:47:50
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:47:52
User entered '06 Oct 2020'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:47:56
User entered empty.	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User entered empty.	System	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:24:49
User closed query 'Per CRIO. Severity is Moderate. Please reconcile and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:24:43
Query 'Per CRIO. Severity is Moderate. Please reconcile and update if applicable.' answered with 'updated ' (Site from CRA).	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:24:48
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:24:41
User opened query 'Per CRIO. Severity is Moderate. Please reconcile and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 14:48:32
User entered 'Grade 3/Severe (Grade 3/Severe)'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:48:46
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:48:48
User entered '0'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:48:49
User entered '0'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:48:51
User entered '0'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:48:53
User entered empty.	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:48:55
User entered empty.	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:49:47
User entered empty.	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:49:48
User entered empty.	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:49:50
User entered '0'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:49:52
User entered '0'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:49:55
User entered '0'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:49:58
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 12:31:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 12:31:49
User entered 'Related (RELATED)' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	27 Oct 2020 12:31:49
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 17:42:40
User entered empty.	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:50:14
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 15:11:18
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 source.' (Site from DM).	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:25:18
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:25:10
User entered 'Related (RELATED)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:25:10
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 14:50:04
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 08:03:45
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 12:31:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 12:31:49
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	27 Oct 2020 12:31:49
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 17:42:40
User entered empty.	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:50:18
User entered 'Not Applicable (NOT APPLICABLE)'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:56:13
DataPoint Un-verified.	Krishna Shah (b) (4)	22 Dec 2020 14:52:11
User entered '1' reason for change: Data Entry Error	(b) (4) Krishna Shah (b) (4)	22 Dec 2020 14:52:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:50:40
User entered '0'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:50:42
User entered '0'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:56:24
User closed query 'Per DM CLR: Other Action Taken = Concomitant Procedure. However, the recorded procedure that match this AE is a Diagnostic procedure rather than a therapeutic procedure. Please update to record the therapeutic procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 08:41:27
Query 'Per DM CLR: Other Action Taken = Concomitant Procedure. However, the recorded procedure that match this AE is a Diagnostic procedure rather than a therapeutic procedure. Please update to record the therapeutic procedure as appropriate. Otherwise, clarify.' answered with 'Patient has had no treatment. Only diagnostic procedures have been done which identified lymphoma (ses AE #3). ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	22 Dec 2020 14:52:59
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	22 Dec 2020 14:52:11
User entered '0' reason for change: Data Entry Error	Krishna Shah (b) (4)	22 Dec 2020 14:52:11
User opened query 'Per DM CLR: Other Action Taken = Concomitant Procedure. However, the recorded procedure that match this AE is a Diagnostic procedure rather than a therapeutic procedure. Please update to record the therapeutic procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 00:37:32
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 14:50:47
User entered '1'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:50:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:50:53
User entered empty.	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:46:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:50:55
User entered 'Subject was scheduled for an ultrasound guided biopsy'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User entered '0'	System	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52
User entered 'I'	System	23 Oct 2020 17:42:40

US3822043

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:51:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:04:52

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Emphysema, LLT: Centrilobular emphysema - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	18 Mar 2021 09:06:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 09:06:45
Data point term sent to Coder	System	17 Mar 2021 17:51:29
User entered 'MODERATE CENTRILOBULAR EMPHYSEMA'	(b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the Solicited Adverse Reaction per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to "NO". Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 10:30:10
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the Solicited Adverse Reaction per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to "NO". Review and update as appropriate. Else, clarify. ' answered with 'Query Resolved' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 15:59:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 15:57:58
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the Solicited Adverse Reaction per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to "NO". Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 09:36:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered '5 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:51:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Mar 2021 17:50:34

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Arteriosclerosis coronary artery, LLT: Coronary artery calcification - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 14:22:46
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 14:22:46
	(b) (4)	
Data point term sent to Coder	System	17 Mar 2021 17:59:33
User entered 'MODERATE-SEVERE CORONARY ARTERIAL CALCIFICATIONS'	(b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the Solicited Adverse Reaction per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to "NO". Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 16:05:46
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the Solicited Adverse Reaction per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to "NO". Review and update as appropriate. Else, clarify. ' answered with 'Query Resolved' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 16:00:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 15:59:57
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the Solicited Adverse Reaction per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to "NO". Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 09:36:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered '5 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
	(b) (4)	
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	17 Mar 2021 17:59:15
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 17:59:15
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	17 Mar 2021 17:58:44
User entered '00:00'	(b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 17:59:15
User entered '5 Sep 2020 00:00'	System	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Kindly record 'Yes' or 'No' in the 'Is the adverse event serious?' data-field. Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 12:19:20
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	22 Mar 2021 15:24:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 15:24:03
Query 'Per CDM: Kindly record 'Yes' or 'No' in the 'Is the adverse event serious?' data-field. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 15:14:51
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	22 Mar 2021 15:14:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 15:14:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	19 Mar 2021 15:59:46
User opened query 'Per CDM: Kindly record 'Yes' or 'No' in the 'Is the adverse event serious?' data-field. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 15:59:33
Query 'Data is required. Please complete.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	17 Mar 2021 17:59:21
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 17:58:44
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:47:12
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Mar 2021 15:24:03
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Mar 2021 15:20:39
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	22 Mar 2021 15:20:39
User entered 'Patient reports that she got a CT done and MD reported MODERATE-SEVERE CORONARY ARTERIAL CALCIFICATIONS. MD monitoring it with no current treatment.' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 15:20:39
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Mar 2021 15:14:26
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 17:58:44

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Mar 2021 15:24:03
User entered '1'	System	22 Mar 2021 15:14:26

US3822043

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:51:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Mar 2021 17:58:44

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:51:52

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:13:53
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:24:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:29:01

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Nov 2020 21:43:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 21:43:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 21:28:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 21:28:49
Data point term sent to Coder Coding entries removed.	System Krishna Shah (b) (4)	18 Nov 2020 21:27:59 18 Nov 2020 21:27:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:33:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:31:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:31:16
Data point term sent to Coder	System	06 Oct 2020 16:30:09

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:52

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Amlodipine'	(b) (4), (b) (6)	06 Oct 2020 16:29:58

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:33:48
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:29:58

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 13:50:47
User closed query 'Please spell out Hypertension' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 13:50:41
Query 'Please spell out Hypertension' answered with 'updated' (Site from CRA).	Krishna Shah (b) (4)	18 Nov 2020 21:27:22
DataPoint Un-verified.	(b) (4)	
	Krishna Shah (b) (4)	18 Nov 2020 21:27:17
User entered 'hypertension' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 21:27:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:33:50
User opened query 'Please spell out Hypertension' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 16:33:43
User entered 'HTN'	(b) (4), (b) (6)	06 Oct 2020 16:29:58

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:33:52
User entered '5'	(b) (4), (b) (6)	06 Oct 2020 16:29:58

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:33:56
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Oct 2020 16:29:58

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:33:58
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:29:58

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:34:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	06 Oct 2020 16:29:58

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:34:06
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:29:58

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:34:09
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Oct 2020 16:29:58

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:52

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:34:11
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:29:58

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:34:14
User entered 'un UNK 2015'	(b) (4), (b) (6)	06 Oct 2020 16:29:58

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:34:16
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:29:58

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:34:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:29:58

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:34:21
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:29:58

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:34:23
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:29:58

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 16:29:58

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 16:29:58

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 16:29:58

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
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.	(b) (4) Coder Import (b) (4) (b) (4)	18 Nov 2020 21:29:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 21:29:48
Data point term sent to Coder Coding entries removed.	System Krishna Shah (b) (4)	18 Nov 2020 21:29:02 18 Nov 2020 21:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:34:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:34:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:34:17
Data point term sent to Coder User entered 'Simvastatin'	System (b) (4), (b) (6)	06 Oct 2020 16:33:16 06 Oct 2020 16:32:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:34:47
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:32:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 13:51:24
User closed query 'Please spell out Hypercholesterolemia' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 13:51:19
Query 'Please spell out Hypercholesterolemia' answered with 'updated' (Site from CRA).	Krishna Shah (b) (4)	18 Nov 2020 21:28:37
User entered 'MIXED HYPERLIPIDEMIA' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 21:28:31
User opened query 'Please spell out Hypercholesterolemia' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 16:35:31
User entered 'HCL'	(b) (4), (b) (6)	06 Oct 2020 16:32:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:35:39
User entered '20'	(b) (4), (b) (6)	06 Oct 2020 16:32:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:35:41
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Oct 2020 16:32:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:35:42
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:32:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:35:45
User entered 'once daily (QD)'	(b) (4), (b) (6)	06 Oct 2020 16:32:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:35:48
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:32:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:35:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Oct 2020 16:32:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:52

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:35:52
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:32:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. '(Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 09:46:33
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 15:18:22
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. '(Site from DM).	(b) (4), (b) (6)	22 Jan 2021 02:40:27
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:35:54
User entered 'un UNK 2009'	(b) (4), (b) (6)	06 Oct 2020 16:32:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:35:56
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:32:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:36:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:32:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:36:04
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:32:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:36:06
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:32:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 16:32:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 16:32:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 16:32:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:36:20
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, PRODUCT: DENOSUMAB, PRODUCTSYNONYM: PROLIA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:34:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:34:17
Data point term sent to Coder User entered 'Prolia'	System (b) (4), (b) (6)	06 Oct 2020 16:33:17 06 Oct 2020 16:33:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:36:22
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:33:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:36:25
User entered 'Osteoporosis'	(b) (4), (b) (6)	06 Oct 2020 16:33:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:36:33
User entered '60'	(b) (4), (b) (6)	06 Oct 2020 16:33:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:36:34
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Oct 2020 16:33:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:33:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:36:36
User entered 'other (OTHER)'	(b) (4), (b) (6)	06 Oct 2020 16:33:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:36:42
User entered 'every 6 months'	(b) (4), (b) (6)	06 Oct 2020 16:33:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:36:44
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	06 Oct 2020 16:33:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:52

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:36:47
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:33:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User closed query 'Per DM CLR: The Con Med start date is prior to the start date of the corresponding Medical History condition of OSTEOPOROSIS. Please reconcile Con Med and Med History Start dates and update applicable eCRFs as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 10:14:36
Query 'Per DM CLR: The Con Med start date is prior to the start date of the corresponding Medical History condition of OSTEOPOROSIS. Please reconcile Con Med and Med History Start dates and update applicable eCRFs as appropriate.' answered with 'med hx updated per patient ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	22 Dec 2020 15:02:05
User opened query 'Per DM CLR: The Con Med start date is prior to the start date of the corresponding Medical History condition of OSTEOPOROSIS. Please reconcile Con Med and Med History Start dates and update applicable eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 21:51:18
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:36:50
User entered 'UN UNK 2017'	(b) (4), (b) (6)	06 Oct 2020 16:33:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:36:52
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:33:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:36:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:33:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:36:58
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:33:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:36:59
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:33:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:33:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:33:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:33:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: IPRATROPIUM BROMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Feb 2021 14:06:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Feb 2021 14:06:59
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	23 Feb 2021 14:05:49 23 Feb 2021 14:05:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: IPRATROPIUM BROMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 12:38:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 12:38:09
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	26 Jan 2021 15:19:54 26 Jan 2021 15:19:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: IPRATROPIUM BROMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 06:44:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 06:44:09
Data point term sent to Coder Coding entries removed.	System Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:31:03 18 Nov 2020 21:30:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:52

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:37:16
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: IPRATROPIUM BROMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:35:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:35:13
Data point term sent to Coder	System	06 Oct 2020 16:34:18
User entered 'Ipratropium Bromide'	(b) (4), (b) (6)	06 Oct 2020 16:34:07

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:05:28
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 14:05:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 13:51:50
User closed query 'Per CRIO source, Prophylaxis is "Yes". Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 13:51:43
Query 'Per CRIO source, Prophylaxis is "Yes". Please reconcile and update CRIO or EDC as applicable.' answered with 'updated' (Site from CRA).	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:30:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:30:31
User opened query 'Per CRIO source, Prophylaxis is "Yes". Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 16:38:04
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:34:07

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF (ALLERGIES). Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 08:03:45
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF (ALLERGIES). Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 14:06:10
User entered 'ALLERGIC RHINITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 14:05:28
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF (ALLERGIES). Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 09:41:34
User closed query 'Per DM CLR: Please review and confirm if this medication is taken for COPD. If yes, please update indication as there is COPD listed in MH ecrf. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 09:47:19
Query 'Per DM CLR: Please review and confirm if this medication is taken for COPD. If yes, please update indication as there is COPD listed in MH ecrf. Please confirm and update as appropriate, otherwise clarify.' answered with 'updated. not used for COPD. This is a nasal spray per source' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 15:20:30
DataPoint Un-verified.	(b) (4), (b) (6)	26 Jan 2021 15:19:41
User entered 'PREVENT ALLERGIES' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 15:19:41
User opened query 'Per DM CLR: Please review and confirm if this medication is taken for COPD. If yes, please update indication as there is COPD listed in MH ecrf. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 02:41:07

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:52

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per CRIO source, Indication is "Supplement" Please reconcile and update CRIO or EDC as applicable.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 13:52:00
	(b) (4), (b) (6)	19 Nov 2020 13:51:56
Query 'Per CRIO source, Indication is "Supplement" Please reconcile and update CRIO or EDC as applicable.' answered with 'updated ' (Site from CRA).	Krishna Shah (b) (4)	18 Nov 2020 21:30:41
	(b) (4)	
User entered 'supplement' reason for change: Data Entry Error	Krishna Shah (b) (4)	18 Nov 2020 21:30:31
	(b) (4)	
User opened query 'Per CRIO source, Indication is "Supplement" Please reconcile and update CRIO or EDC as applicable.' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 16:39:12
	(b) (4), (b) (6)	18 Nov 2020 16:38:15
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:38:07
User entered 'Allergies'	(b) (4), (b) (6)	06 Oct 2020 16:34:07

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:38:49
User entered '42'	(b) (4), (b) (6)	06 Oct 2020 16:34:07

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:38:51
User entered 'ug (ug)'	(b) (4), (b) (6)	06 Oct 2020 16:34:07

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:38:58
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:34:07

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 13:52:07
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:41:48
User entered 'as needed (PRN)' reason for change:	Krishna Shah (b) (4)	18 Nov 2020 21:41:48
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:39:06
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	06 Oct 2020 16:34:07

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User closed query 'Per CRIO source, Frequency is PRN. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 13:52:18
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 13:52:15
Query 'Per CRIO source, Frequency is PRN. Please reconcile and update CRIO or EDC as applicable.' answered with 'updated ' (Site from CRA).	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:41:54
User opened query 'Per CRIO source, Frequency is PRN. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 16:39:38
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:34:07

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 09:48:16
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'ipratropium bromide is a nasal spray' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 15:20:05
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 02:40:48
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:39:41
User entered 'Nasal (NASAL)'	(b) (4), (b) (6)	06 Oct 2020 16:34:07

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:39:44
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:34:07

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:39:46
User entered 'un UNK 2012'	(b) (4), (b) (6)	06 Oct 2020 16:34:07

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:39:49
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:34:07

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:39:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:34:07

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:39:53
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:34:07

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:39:55
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:34:07

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:34:07

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:34:07

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:34:07

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:41:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 04:46:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 04:46:24
Data point term sent to Coder	System	06 Oct 2020 16:36:19
User entered 'Sertraline'	(b) (4), (b) (6)	06 Oct 2020 16:35:22

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:41:17
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:35:22

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:41:19
User entered 'Depression and anxiety'	(b) (4), (b) (6)	06 Oct 2020 16:35:22

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:41:20
User entered '50'	(b) (4), (b) (6)	06 Oct 2020 16:35:22

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:41:22
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Oct 2020 16:35:22

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:41:25
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:35:22

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:41:26
User entered 'once daily (QD)'	(b) (4), (b) (6)	06 Oct 2020 16:35:22

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:41:29
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:35:22

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:41:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Oct 2020 16:35:22

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:52

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:41:34
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:35:22

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User closed query 'Per DM CLR: The Con Med start date is prior to the start date of the corresponding Medical History condition of MIXED ANXIETY AND DEPRESSIVE DISORDER. Please reconcile Con Med and Med History Start dates and update applicable eCRFs as appropriate.' (Site from DM). Query 'Per DM CLR: The Con Med start date is prior to the start date of the corresponding Medical History condition of MIXED ANXIETY AND DEPRESSIVE DISORDER. Please reconcile Con Med and Med History Start dates and update applicable eCRFs as appropriate.' answered with 'med hx updated per patient ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 10:15:08
User opened query 'Per DM CLR: The Con Med start date is prior to the start date of the corresponding Medical History condition of MIXED ANXIETY AND DEPRESSIVE DISORDER. Please reconcile Con Med and Med History Start dates and update applicable eCRFs as appropriate.' (Site from DM). DataPoint Verified.	Krishna Shah (b) (4) (b) (4)	22 Dec 2020 15:02:24
User entered 'un UNK 1997'	(b) (4), (b) (6)	26 Nov 2020 21:53:24
	(b) (4), (b) (6)	18 Nov 2020 16:41:37
	(b) (4), (b) (6)	06 Oct 2020 16:35:22

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:41:39
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:35:22

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:41:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:35:22

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:41:42
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:35:22

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:41:45
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:35:22

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 16:35:22

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 16:35:22

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 16:35:22

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 16:42:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 15:11:49
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 15:11:49
	(b) (4)	
Data point term sent to Coder	System	06 Oct 2020 16:36:20
User entered 'Lorazepam'	(b) (4), (b) (6)	06 Oct 2020 16:36:17

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:42:19
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:36:17

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:42:21
User entered 'Restless leg'	(b) (4), (b) (6)	06 Oct 2020 16:36:17

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 14:01:47
User closed query 'Per CRIO source, Does is 1mg. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:01:43
Query 'Per CRIO source, Does is 1mg. Please reconcile and update CRIO or EDC as applicable.' answered with 'updated ' (Site from CRA).	Krishna Shah (b) (4)	18 Nov 2020 21:42:57
User entered '1' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 16:42:51
User opened query 'Per CRIO source, Does is 1mg. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).		
User entered '0.25'	(b) (4), (b) (6)	06 Oct 2020 16:36:17

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:42:54
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Oct 2020 16:36:17

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:42:56
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:36:17

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:43:00
User entered 'as needed (PRN)'	(b) (4), (b) (6)	06 Oct 2020 16:36:17

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:43:01
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:36:17

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:43:04
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Oct 2020 16:36:17

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:52

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:43:06
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:36:17

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 14:01:58
User closed query 'Per CRIO source, Start Date is UNUNK2018. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:01:52
Query 'Per CRIO source, Start Date is UNUNK2018. Please reconcile and update CRIO or EDC as applicable.' answered with 'updated' (Site from CRA).	Krishna Shah (b) (4)	18 Nov 2020 21:43:01
User entered 'UN UNK 2018' reason for change:	(b) (4)	
Data Entry Error	Krishna Shah (b) (4)	18 Nov 2020 21:42:51
	(b) (4)	
User opened query 'Per CRIO source, Start Date is UNUNK2018. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 16:43:53
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:36:17

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:02:01
User closed query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	18 Nov 2020 21:43:08
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:43:08
User entered '0' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:43:08
User opened query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	18 Nov 2020 21:42:51
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:43:57
User entered '1'	(b) (4), (b) (6)	06 Oct 2020 16:36:17

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:36:17

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:02
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:36:17

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:04
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:36:17

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:36:17

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:36:17

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:36:17

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:51:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Nov 2020 21:44:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 21:44:49
Data point term sent to Coder	System	18 Nov 2020 21:44:14
Coding entries removed.	Krishna Shah (b) (4)	18 Nov 2020 21:43:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 16:38:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 16:38:18
Data point term sent to Coder	System	06 Oct 2020 16:37:24
User entered 'Omeprazole'	(b) (4), (b) (6)	06 Oct 2020 16:37:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:51:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:21
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:37:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:51:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User closed query 'Per CRIO source, Indication is GERD. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 14:02:22
Query 'Per CRIO source, Indication is GERD. Please reconcile and update CRIO or EDC as applicable.' answered with 'updated' (Site from CRA).	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:43:39
User entered 'GASTROESOPHAGEAL REFLUX DISEASE' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:43:32
User opened query 'Per CRIO source, Indication is GERD. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 16:44:53
User entered 'UNK'	(b) (4), (b) (6)	06 Oct 2020 16:37:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:51:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:57
User entered '40'	(b) (4), (b) (6)	06 Oct 2020 16:37:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:51:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:44:59
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Oct 2020 16:37:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:51:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:45:02
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:37:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:51:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:45:05
User entered 'once daily (QD)'	(b) (4), (b) (6)	06 Oct 2020 16:37:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:51:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:45:09
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:37:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:51:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:45:11
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Oct 2020 16:37:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:51:52

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:45:13
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:37:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:51:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 09:48:47
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' answered with 'updated med hx' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 15:21:25
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 02:43:03
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:45:15
User entered 'un UNK 2012'	(b) (4), (b) (6)	06 Oct 2020 16:37:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:45:18
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:37:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:45:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:37:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:51:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:45:22
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:37:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:51:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:45:23
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:37:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:51:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 16:37:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 16:37:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 16:37:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:51:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
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)	18 Nov 2020 21:45:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 21:45:49
Data point term sent to Coder Coding entries removed.	System Krishna Shah (b) (4)	18 Nov 2020 21:45:15 18 Nov 2020 21:45:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:45:45
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)	06 Oct 2020 16:39:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:39:23
Data point term sent to Coder User entered 'Aspirin'	System (b) (4), (b) (6)	06 Oct 2020 16:38:24 06 Oct 2020 16:37:40

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:51:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User closed query 'Per CRIO source, Prophylaxis is "No". Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:03:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 14:03:46
Query 'Per CRIO source, Prophylaxis is "No". Please reconcile and update CRIO or EDC as applicable.' answered with 'CRIO updated ' (Site from CRA).	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:44:59
User opened query 'Per CRIO source, Prophylaxis is "No". Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 16:46:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:37:40

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:51:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 14:03:57
DataPoint Un-verified.	Krishna Shah (b) (4)	18 Nov 2020 21:45:05
	(b) (4)	
User entered 'Cardiac health' reason for change:	Krishna Shah (b) (4)	18 Nov 2020 21:45:05
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:11
	(b) (4), (b) (6)	
User entered 'Supplement'	(b) (4), (b) (6)	06 Oct 2020 16:37:40

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:51:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:46:13
User entered '81'	(b) (4), (b) (6)	06 Oct 2020 16:37:40

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:51:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:46:15
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Oct 2020 16:37:40

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:51:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:46:17
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:37:40

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:51:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:46:24
User entered 'once daily (QD)'	(b) (4), (b) (6)	06 Oct 2020 16:37:40

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:51:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:46:25
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:37:40

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:51:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Oct 2020 16:37:40

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:51:52

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:46:30
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:37:40

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:46:28
User entered 'un UNK 2011'	(b) (4), (b) (6)	06 Oct 2020 16:37:40

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:46:34
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:37:40

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:46:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:37:40

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:51:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:46:39
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:37:40

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:51:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:46:41
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:37:40

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:51:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 16:37:40

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 16:37:40

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 16:37:40

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:51:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:39:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:39:23
Data point term sent to Coder User entered 'Vitamin D3'	System (b) (4), (b) (6)	06 Oct 2020 16:38:26 06 Oct 2020 16:38:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:51:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:38:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:51:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:05
User entered 'Supplement'	(b) (4), (b) (6)	06 Oct 2020 16:38:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:51:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:08
User entered '1000'	(b) (4), (b) (6)	06 Oct 2020 16:38:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:51:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 07:17:32
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate.' answered with 'updated' (Site from DM).	Krishna Shah (b) (4) (b) (4)	21 Dec 2020 22:01:38
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	21 Dec 2020 22:01:31
User entered 'IU (IU)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	21 Dec 2020 22:01:31
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 21:54:10
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:10
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Oct 2020 16:38:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:51:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:11
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:38:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:51:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:15
User entered 'once daily (QD)'	(b) (4), (b) (6)	06 Oct 2020 16:38:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:51:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:17
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:38:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:51:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Oct 2020 16:38:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:51:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:26
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:38:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:31
User entered 'un UNK 2010'	(b) (4), (b) (6)	06 Oct 2020 16:38:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:45
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:38:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:38:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:51:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:52
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:38:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:51:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:47:54
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:38:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:51:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 16:38:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 16:38:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 16:38:15

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 16:48:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 16:40:25
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 16:40:25
	(b) (4)	
Data point term sent to Coder	System	06 Oct 2020 16:39:27
User entered 'Women's Multi Vitamin'	(b) (4), (b) (6)	06 Oct 2020 16:38:46

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User closed query 'Per CRIO source, Prophylaxis is "No". Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:04:34
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 14:04:31
Query 'Per CRIO source, Prophylaxis is "No". Please reconcile and update CRIO or EDC as applicable.' answered with 'CRIO updated ' (Site from CRA).	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:47:24
User opened query 'Per CRIO source, Prophylaxis is "No". Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 16:48:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:38:46

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:48:26
User entered 'Supplement'	(b) (4), (b) (6)	06 Oct 2020 16:38:46

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:48:28
User entered 'I'	(b) (4), (b) (6)	06 Oct 2020 16:38:46

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:48:31
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	06 Oct 2020 16:38:46

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:48:39
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:38:46

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:48:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	06 Oct 2020 16:38:46

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:48:47
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:38:46

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:48:44
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Oct 2020 16:38:46

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:52

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:48:51
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:38:46

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:48:53
User entered 'un UNK 2010'	(b) (4), (b) (6)	06 Oct 2020 16:38:46

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:48:55
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:38:46

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:48:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:38:46

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:48:59
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:38:46

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:49:01
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:38:46

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 16:38:46

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 16:38:46

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 16:38:46

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:51:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 16:49:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 16:40:25
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 16:40:25
	(b) (4)	
Data point term sent to Coder	System	06 Oct 2020 16:39:27
User entered 'calcium'	(b) (4), (b) (6)	06 Oct 2020 16:39:06

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:51:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:49:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:39:06

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:51:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:49:26
User entered 'Supplement'	(b) (4), (b) (6)	06 Oct 2020 16:39:06

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:51:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:49:29
User entered '600'	(b) (4), (b) (6)	06 Oct 2020 16:39:06

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:51:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:49:31
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Oct 2020 16:39:06

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:51:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:49:33
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:39:06

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:51:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:49:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	06 Oct 2020 16:39:06

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:51:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:49:37
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:39:06

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:51:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:49:40
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Oct 2020 16:39:06

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:51:52

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:49:43
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:39:06

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:49:45
User entered 'un UNK 2010'	(b) (4), (b) (6)	06 Oct 2020 16:39:06

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4)	18 Nov 2020 16:49:47
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:39:06

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:49:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:39:06

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:51:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:49:51
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:39:06

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:51:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:49:53
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:39:06

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:51:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 16:39:06

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 16:39:06

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 16:39:06

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:51:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:50:10
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:41:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:41:16
Data point term sent to Coder User entered 'Probiotic'	System (b) (4), (b) (6)	06 Oct 2020 16:40:27 06 Oct 2020 16:39:30

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:51:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:50:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:39:30

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:51:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:50:20
User entered 'Supplement'	(b) (4), (b) (6)	06 Oct 2020 16:39:30

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:51:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:50:23
User entered 'I'	(b) (4), (b) (6)	06 Oct 2020 16:39:30

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:51:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:50:27
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	06 Oct 2020 16:39:30

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:51:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:50:28
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:39:30

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:51:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:50:30
User entered 'once daily (QD)'	(b) (4), (b) (6)	06 Oct 2020 16:39:30

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:51:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:50:34
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:39:30

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:51:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:50:36
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Oct 2020 16:39:30

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:51:52

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:50:38
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:39:30

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:51:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User closed query 'Per CRIO source, Start Date is 2018. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:05:06
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 14:05:01
Query 'Per CRIO source, Start Date is 2018. Please reconcile and update CRIO or EDC as applicable.' answered with 'updated per source. ' (Site from CRA).	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:51:03
User entered 'UN UNK 2018' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:50:56
User opened query 'Per CRIO source, Start Date is 2018. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 16:51:02
User entered 'un UNK 2008'	(b) (4), (b) (6)	06 Oct 2020 16:39:30

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:51:07
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:39:30

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:51:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:39:30

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:51:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:51:12
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:39:30

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:51:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:51:14
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:39:30

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:51:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 16:39:30

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 16:39:30

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 16:39:30

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:51:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:51:35
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE RGE (CHO), PRODUCTSYNONYM: SHINGRIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:41:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:41:15
Data point term sent to Coder	System	06 Oct 2020 16:40:29
User entered 'Shingrix'	(b) (4), (b) (6)	06 Oct 2020 16:40:04

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:51:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:51:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:40:04

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:51:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:51:40
User entered 'Vaccine'	(b) (4), (b) (6)	06 Oct 2020 16:40:04

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:51:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:51:43
User entered 'UNK'	(b) (4), (b) (6)	06 Oct 2020 16:40:04

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:51:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:51:47
User entered 'mL (mL)'	(b) (4), (b) (6)	06 Oct 2020 16:40:04

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:51:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:51:50
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:40:04

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:51:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:51:56
User entered 'once (ONCE)'	(b) (4), (b) (6)	06 Oct 2020 16:40:04

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:51:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:51:58
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:40:04

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:51:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:00
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	06 Oct 2020 16:40:04

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:51:52

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:04
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:40:04

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:06
User entered '21 Feb 2019'	(b) (4), (b) (6)	06 Oct 2020 16:40:04

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:07
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:40:04

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:09
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:40:04

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:51:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:12
User entered '21 Feb 2019'	(b) (4), (b) (6)	06 Oct 2020 16:40:04

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:51:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:14
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:40:04

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:51:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:46
User entered empty.	System	06 Oct 2020 16:40:04

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:46
User entered empty.	System	06 Oct 2020 16:40:04

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:46
User entered empty.	System	06 Oct 2020 16:40:04

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:51:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: FLUTICASONE FUROATE;UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: TRELEGY ELLIPTA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Jan 2021 15:30:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 15:30:18
Data point term sent to Coder	System	26 Jan 2021 15:29:04
Coding entries removed.	(b) (4), (b) (6)	26 Jan 2021 15:29:03
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: FLUTICASONE FUROATE;UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: TRELEGY ELLIPTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 21:52:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 21:52:48
Data point term sent to Coder	System	18 Nov 2020 21:52:23
Coding entries removed.	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:51:47
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:51:52

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: FLUTICASONE FUROATE;UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: TRELEGY ELLIPTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 16:42:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 16:42:21
Data point term sent to Coder	System	06 Oct 2020 16:41:30
User entered 'Trelegy Ellipta'	(b) (4), (b) (6)	06 Oct 2020 16:40:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:51:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:52:41
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:40:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:51:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 09:49:13
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'Updated with COPD. Patient has COPD. Not asthma. Per source.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 15:29:55
DataPoint Un-verified.	(b) (4), (b) (6)	26 Jan 2021 15:29:03
User entered 'COPD' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 15:29:03
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 02:47:11
User closed query 'Per CRIO source, Indication is "Asthma". Please reconcile and update CRIO or EDC as applicable. Please also note, per Medical History this is reported as COPD and not Asthma. Please reconcile and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:06:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 14:06:19
Query 'Per CRIO source, Indication is "Asthma". Please reconcile and update CRIO or EDC as applicable. Please also note, per Medical History this is reported as COPD and not Asthma. Please reconcile and update if applicable.' answered with 'updated per source' (Site from CRA).	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:51:54
User entered 'ASthma' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:51:47
User opened query 'Per CRIO source, Indication is "Asthma". Please reconcile and update CRIO or EDC as applicable. Please also note, per Medical History this is reported as COPD and not Asthma. Please reconcile and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 16:55:28

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:51:52

[Indication](#)

Audit	User	Time (GMT)
User entered 'COPD'	(b) (4), (b) (6)	06 Oct 2020 16:40:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:51:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User closed query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components using slash (e.g. 5/325).' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 07:20:35
Query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components using slash (e.g. 5/325).' answered with 'updated' (Site from DM).	Krishna Shah (b) (4) (b) (4)	21 Dec 2020 22:02:54
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	21 Dec 2020 22:02:48
User entered '100/62.5/25' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	21 Dec 2020 22:02:48
User opened query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components using slash (e.g. 5/325).' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 21:54:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:55:50
User entered '100'	(b) (4), (b) (6)	06 Oct 2020 16:40:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:51:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:55:52
User entered 'ug (ug)'	(b) (4), (b) (6)	06 Oct 2020 16:40:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:51:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:55:55
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:40:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:51:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:55:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	06 Oct 2020 16:40:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:51:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:55:59
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:40:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:51:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:56:02
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	06 Oct 2020 16:40:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:51:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:56:04
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:40:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:56:06
User entered 'un UNK 2018'	(b) (4), (b) (6)	06 Oct 2020 16:40:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:56:11
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:40:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:56:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:40:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:51:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:56:16
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:40:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:51:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:56:18
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:40:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:51:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 16:40:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 16:40:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 16:40:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:56:39
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:42:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:42:21
Data point term sent to Coder User entered 'Albuterol'	System (b) (4), (b) (6)	06 Oct 2020 16:41:31 06 Oct 2020 16:41:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:56:41
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:41:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:56:43
User entered 'COPD'	(b) (4), (b) (6)	06 Oct 2020 16:41:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:56:46
User entered '90'	(b) (4), (b) (6)	06 Oct 2020 16:41:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:56:48
User entered 'ug (ug)'	(b) (4), (b) (6)	06 Oct 2020 16:41:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:56:50
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:41:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:56:54
User entered 'as needed (PRN)'	(b) (4), (b) (6)	06 Oct 2020 16:41:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:56:56
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:41:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:56:58
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	06 Oct 2020 16:41:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:57:01
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:41:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:57:03
User entered 'un UNK 2018'	(b) (4), (b) (6)	06 Oct 2020 16:41:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:57:05
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:41:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:57:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:41:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:57:08
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:41:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:57:10
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:41:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:41:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:41:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:41:14

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:57:34
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM;SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL;IPRATROPIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 10:56:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 10:56:23
Data point term sent to Coder	System	06 Oct 2020 16:42:31
User entered 'Ipratropium-albuterol'	(b) (4), (b) (6)	06 Oct 2020 16:41:48

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:57:36
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:41:48

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:57:38
User entered 'COPD'	(b) (4), (b) (6)	06 Oct 2020 16:41:48

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 08:04:17
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'This is the dose the patient provided to the clinic' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 14:08:53
User entered '90' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 14:08:47
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 09:42:38
User closed query 'Per CDM: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 100/20). Thankyou.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 19:19:44
Query 'Per CDM: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 100/20). Thankyou.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 20:07:34
User entered '0.5/3' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 20:07:29
User opened query 'Per CDM: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 100/20). Thankyou.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 13:25:12
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 100/20). Thankyou.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 13:22:49

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:52

[Dose per administration](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 100/20). ' answered with 'Per source the dose is 90mcg' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	26 Jan 2021 15:30:57
	(b) (4), (b) (6)	26 Jan 2021 15:30:37
User entered '90' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 15:30:37
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 100/20). ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 02:50:39
	(b) (4), (b) (6)	18 Nov 2020 16:57:40
User entered '3'	(b) (4), (b) (6)	06 Oct 2020 16:41:48

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 14:08:47
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 20:07:29
DataPoint Un-verified.	(b) (4), (b) (6)	26 Jan 2021 15:30:37
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 15:30:37
User closed query 'Per CRIO source, Dose unit is mg. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:06:50
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 14:06:40
Query 'Per CRIO source, Dose unit is mg. Please reconcile and update CRIO or EDC as applicable.' answered with 'updated per source ' (Site from CRA).	Krishna Shah (b) (4)	18 Nov 2020 21:52:23
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Krishna Shah (b) (4)	18 Nov 2020 21:52:15
	(b) (4)	
User opened query 'Per CRIO source, Dose unit is mg. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 16:58:04
User entered 'mL (mL)'	(b) (4), (b) (6)	06 Oct 2020 16:41:48

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:58:07
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:41:48

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:58:09
User entered 'as needed (PRN)'	(b) (4), (b) (6)	06 Oct 2020 16:41:48

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:58:11
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:41:48

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:58:13
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	06 Oct 2020 16:41:48

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:58:16
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:41:48

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:58:18
User entered 'UN UNK 2018'	(b) (4), (b) (6)	06 Oct 2020 16:41:48

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:58:20
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:41:48

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:58:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:41:48

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:58:26
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:41:48

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:58:30
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:41:48

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:41:48

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:41:48

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:41:48

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 16:58:51
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: BUDESONIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 16:44:19
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 16:44:19
	(b) (4)	
Data point term sent to Coder	System	06 Oct 2020 16:43:33
User entered 'Budesonide'	(b) (4), (b) (6)	06 Oct 2020 16:42:42

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:58:54
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:42:42

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:58:56
User entered 'COPD'	(b) (4), (b) (6)	06 Oct 2020 16:42:42

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 15:31:25
User entered '0.5' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 15:31:25
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:58:58
User entered '2'	(b) (4), (b) (6)	06 Oct 2020 16:42:42

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User closed query 'Per DM CLR: Please provide the dose in MG for this medication instead of ML as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 09:54:49
Query 'Per DM CLR: Please provide the dose in MG for this medication instead of ML as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Per source in CRIO dose is 0.5mg' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 15:31:41
DataPoint Un-verified.	(b) (4), (b) (6)	26 Jan 2021 15:31:25
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 15:31:25
User opened query 'Per DM CLR: Please provide the dose in MG for this medication instead of ML as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 02:52:47
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:59:00
User entered 'mL (mL)'	(b) (4), (b) (6)	06 Oct 2020 16:42:42

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:59:05
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:42:42

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User closed query 'Per CRIO source, frequency is PRN. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:07:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 14:07:21
Query 'Per CRIO source, frequency is PRN. Please reconcile and update CRIO or EDC as applicable.' answered with 'updated' (Site from CRA).	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:50:17
User entered 'as needed (PRN)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:50:06
User opened query 'Per CRIO source, frequency is PRN. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 16:59:29
User entered 'twice daily (BID)'	(b) (4), (b) (6)	06 Oct 2020 16:42:42

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:59:34
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:42:42

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:59:37
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	06 Oct 2020 16:42:42

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:59:39
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:42:42

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:59:41
User entered 'UN UNK 2018'	(b) (4), (b) (6)	06 Oct 2020 16:42:42

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:59:43
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:42:42

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:59:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:42:42

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:59:46
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:42:42

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:59:48
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:42:42

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 21:50:06
User entered '2'	System	06 Oct 2020 16:42:42

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 21:50:06
User entered '1'	System	06 Oct 2020 16:42:42

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 21:50:06
User entered '804 (804)'	System	06 Oct 2020 16:42:42

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:55
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PERTUSSIS VACCINES, PRODUCT: DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE;TETANUS VACCINE TOXOID, PRODUCTSYNONYM: DIPHTHERIA TETANUS PERTUSSIS VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 12:54:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 12:54:58
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User closed query 'Please add source in CRIO for TDAP, Influenza, and Pneumococcal' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:11:10
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 14:11:04
Query 'Please add source in CRIO for TDAP, Influenza, and Pneumococcal' answered with 'Please see scanned med hx under patient header for source of all vaccines. ' (Site from CRA).	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:46:37
User opened query 'Please add source in CRIO for TDAP, Influenza, and Pneumococcal' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 17:04:09
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PERTUSSIS VACCINES, PRODUCT: DIPHTHERIA VACCINE;PERTUSSIS VACCINE;TETANUS VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:44:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:44:20
Data point term sent to Coder	System	06 Oct 2020 16:43:36
User entered 'Diphtheria, tetanus, pertussis'	(b) (4), (b) (6)	06 Oct 2020 16:43:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:11:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:43:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:11:57
User entered 'Vaccine'	(b) (4), (b) (6)	06 Oct 2020 16:43:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:11:37
User entered 'UNK'	(b) (4), (b) (6)	06 Oct 2020 16:43:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:12:01
User entered 'mL (mL)'	(b) (4), (b) (6)	06 Oct 2020 16:43:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:12:07
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:43:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:12:04
User entered 'once (ONCE)'	(b) (4), (b) (6)	06 Oct 2020 16:43:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:12:10
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:43:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:12:13
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	06 Oct 2020 16:43:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:52

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:12:20
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:43:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:12:24
User entered '01 May 2012'	(b) (4), (b) (6)	06 Oct 2020 16:43:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:12:29
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:43:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:12:39
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:43:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:12:42
User entered '1 May 2012'	(b) (4), (b) (6)	06 Oct 2020 16:43:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:12:45
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:43:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:55
User entered empty.	System	06 Oct 2020 16:43:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:55
User entered empty.	System	06 Oct 2020 16:43:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:55
User entered empty.	System	06 Oct 2020 16:43:31

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:57
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 06:02:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 06:02:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:13:05
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 21:23:02
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 21:23:02
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)	06 Oct 2020 16:45:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:45:24
Data point term sent to Coder User entered 'Influenza'	System (b) (4), (b) (6)	06 Oct 2020 16:44:36 06 Oct 2020 16:44:16

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:13:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:44:16

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:13:22
User entered 'Vaccine'	(b) (4), (b) (6)	06 Oct 2020 16:44:16

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:13:27
User entered 'UNK'	(b) (4), (b) (6)	06 Oct 2020 16:44:16

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:13:31
User entered 'mL (mL)'	(b) (4), (b) (6)	06 Oct 2020 16:44:16

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:13:35
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:44:16

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:13:39
User entered 'as needed (PRN)'	(b) (4), (b) (6)	06 Oct 2020 16:44:16

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:13:42
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:44:16

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:13:50
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	06 Oct 2020 16:44:16

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:52

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:13:54
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:44:16

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:14:00
User entered '20 Oct 2018'	(b) (4), (b) (6)	06 Oct 2020 16:44:16

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:14:04
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:44:16

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:14:13
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:44:16

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:14:17
User entered '20 Oct 2018'	(b) (4), (b) (6)	06 Oct 2020 16:44:16

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:14:27
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:44:16

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:57
User entered empty.	System	06 Oct 2020 16:44:16

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:57
User entered empty.	System	06 Oct 2020 16:44:16

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:22:57
User entered empty.	System	06 Oct 2020 16:44:16

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:03
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:14:43
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)	06 Oct 2020 16:46:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:46:30
Data point term sent to Coder	System	06 Oct 2020 16:45:41
User entered 'Pneumococcal'	(b) (4), (b) (6)	06 Oct 2020 16:45:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:03
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:14:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:45:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:03
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:14:59
User entered 'Vaccine'	(b) (4), (b) (6)	06 Oct 2020 16:45:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:03
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:15:04
User entered 'UNK'	(b) (4), (b) (6)	06 Oct 2020 16:45:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:03
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:15:13
User entered 'mL (mL)'	(b) (4), (b) (6)	06 Oct 2020 16:45:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:03
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:15:17
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:45:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:03
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:15:21
User entered 'once (ONCE)'	(b) (4), (b) (6)	06 Oct 2020 16:45:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:03
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:15:24
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:45:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:03
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:15:27
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	06 Oct 2020 16:45:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:52

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:03
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:15:32
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:45:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:03
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:15:36
User entered '09 Feb 2016'	(b) (4), (b) (6)	06 Oct 2020 16:45:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:03
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:15:40
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:45:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:03
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:15:56
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:45:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:03
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:16:05
User entered '9 Feb 2016'	(b) (4), (b) (6)	06 Oct 2020 16:45:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:03
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:16:08
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:45:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:03
User entered empty.	System	06 Oct 2020 16:45:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:03
User entered empty.	System	06 Oct 2020 16:45:38

US3822043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:51:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:23:03
User entered empty.	System	06 Oct 2020 16:45:38

US3822043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:51:52

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:13:53
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:48:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:42:51
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	06 Oct 2020 20:29:45

US3822043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:51:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:48:24
User entered '05 Sep 2020'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:43:24

US3822043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:51:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
User closed query 'Per CDM: On Concomitant Procedures form, site has recorded procedure 'Chest CT for Lung Cancer Screening' on 05Sep2020. This procedure revealed the following 2 conditions (not previously recorded on MH log): MODERATE CENTRIOBULAR EMPHYSEMA and MODERATE-SEVERE CORONARY ARTERIAL CALCIFICATIONS. Per CCGs, any abnormal findings must be added onto AE log. Therefore, please verify data and if appropriate, consider adding 'Moderate Centrilobular Emphysema' and 'Moderate-Severe Coronary Arterial Calcifications' as two separate entries on AE log. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:58:09
Query 'Per CDM: On Concomitant Procedures form, site has recorded procedure 'Chest CT for Lung Cancer Screening' on 05Sep2020. This procedure revealed the following 2 conditions (not previously recorded on MH log): MODERATE CENTRIOBULAR EMPHYSEMA and MODERATE-SEVERE CORONARY ARTERIAL CALCIFICATIONS. Per CCGs, any abnormal findings must be added onto AE log. Therefore, please verify data and if appropriate, consider adding 'Moderate Centrilobular Emphysema' and 'Moderate-Severe Coronary Arterial Calcifications' as two separate entries on AE log. Thank you.' answered with 'updated.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 18:02:55

US3822043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:51:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: On Concomitant Procedures form, site has recorded procedure 'Chest CT for Lung Cancer Screening' on 05Sep2020. This procedure revealed the following 2 conditions (not previously recorded on MH log): MODERATE CENTRIOLOBULAR EMPHYSEMA and MODERATE-SEVERE CORONARY ARTERIAL CALCIFICATIONS. Per CCGs, any abnormal findings must be added onto AE log. Therefore, please verify data and if appropriate, consider adding 'Moderate Centrilobular Emphysema' and 'Moderate-Severe Coronary Arterial Calcifications' as two separate entries on AE log. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 15:38:35
Query 'Per CDM : Indication = Medical History, however, the noted medical condition/Procedure/Surgery is not recorded with separate entries on the MH eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. Medical History) as appropriate, otherwise clarify. Thank you!' canceled (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 15:37:42
User opened query 'Per CDM : Indication = Medical History, however, the noted medical condition/Procedure/Surgery is not recorded with separate entries on the MH eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. Medical History) as appropriate, otherwise clarify. Thank you!' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 11:12:35
User closed query 'Please contact subject as soon as possible instead of waiting until next scheduled phone call. Due to the subject having an SAE, we need as much information as possible.' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 16:38:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:54:24
Query 'Please contact subject as soon as possible instead of waiting until next scheduled phone call. Due to the subject having an SAE, we need as much information as possible.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 14:07:26

PRODUCTION RELEASE (v12.003
EAB) (1725)

2300 of 2457

US3822043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:51:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 14:07:21
User entered 'CT CHEST FOR LUNG CANCER SCREENING - Moderate centrilobular emphysema, Moderate-severe coronary arterial calcifications. Normal heart size.' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 14:07:21
User opened query 'Please contact subject as soon as possible instead of waiting until next scheduled phone call. Due to the subject having an SAE, we need as much information as possible.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:18:26
User closed query 'Per Hem/Onc note on 21OCT2020 visit, subject was to have additional CT imaging. Has this been completed? if so, kindly obtain records and update EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:18:26
Query 'Per Hem/Onc note on 21OCT2020 visit, subject was to have additional CT imaging. Has this been completed? if so, kindly obtain records and update EDC. Thank you.' answered with 'Will confirm with patient at next phone call and update if completed.' (Site from CRA).	Krishna Shah (b) (4) (b) (4)	18 Nov 2020 21:55:15
User opened query 'Per Hem/Onc note on 21OCT2020 visit, subject was to have additional CT imaging. Has this been completed? if so, kindly obtain records and update EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 20:51:53
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:48:24
User entered 'CT Chest'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:43:24

US3822043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:51:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:48:24
User entered 'Medical History (MH)'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:43:24

US3822043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:51:52

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:48:24
User entered empty.	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:43:24

US3822043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:51:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:22:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:48:24
User entered '02 Oct 2020'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:43:59

US3822043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:51:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:22:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:48:24
User entered 'Ultrasounds guided core biopsy'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:43:59

US3822043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:51:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:22:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:48:24
User entered 'Adverse Event (AE)'	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:43:59

US3822043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:51:52

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:22:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:48:24
User entered empty.	Kelly Woodell (b) (4) (b) (4)	23 Oct 2020 17:43:59

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'USA-US126-2020-MRNA-1273-P301000006'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Yes (Y)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Yes (Y)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Christina'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Kennelly'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
User closed query 'No data has been updated for address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:42:30
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:29
	(b) (4)	
Query 'No data has been updated for address fields.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 15:55:36
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
User opened query 'No data has been updated for address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:50:58
	(b) (4), (b) (6)	
User closed query 'Please add entry for each address field.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:50:58
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Query 'Please add entry for each address field.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:42:01
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User opened query 'Please add entry for each address field.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 15:54:13
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:38
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User closed query 'Kindly update the rest of this page if you are able to. Thank you.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:54:57
	(b) (4), (b) (6)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: [Street](#)

Audit	User	Time (GMT)
Query 'Kindly update the rest of this page if you are able to. Thank you.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	10 Nov 2020 17:12:26
User entered '6060 Piedmont Row Drive South'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
User opened query 'Kindly update the rest of this page if you are able to. Thank you.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 19:03:36

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:33
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User entered 'Charlotte'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
	(b) (4)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:34
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User entered 'NC'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
	(b) (4)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:36
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User entered '28210'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
	(b) (4)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:46:34
User entered 'US'	System	26 Oct 2020 21:07:42

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	26 Jan 2021 18:54:22
User entered '6'	System	15 Jan 2021 17:11:01
User entered '5'	System	22 Dec 2020 20:29:38
User entered '4'	System	24 Nov 2020 19:28:52
User entered '3'	System	19 Nov 2020 14:28:16
User entered '2'	System	28 Oct 2020 13:46:45
User entered '1'	System	26 Oct 2020 21:07:42

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'USA-US126-2020-MRNA-1273-P301000006'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Yes (Y)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Yes (Y)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Christina'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Kennelly'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
User closed query 'No data has been updated for address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:42:30
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:29
	(b) (4)	
Query 'No data has been updated for address fields.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 15:55:36
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
User opened query 'No data has been updated for address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:50:58
	(b) (4), (b) (6)	
User closed query 'Please add entry for each address field.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:50:58
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Query 'Please add entry for each address field.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:42:01
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User opened query 'Please add entry for each address field.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 15:54:13
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:38
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User closed query 'Kindly update the rest of this page if you are able to. Thank you.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:54:57
	(b) (4), (b) (6)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Site Address: Street](#)

Audit	User	Time (GMT)
Query 'Kindly update the rest of this page if you are able to. Thank you.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	10 Nov 2020 17:12:26
User entered '6060 Piedmont Row Drive South'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
User opened query 'Kindly update the rest of this page if you are able to. Thank you.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 19:03:36

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:33
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
User entered 'Charlotte'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
	(b) (4)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:34
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User entered 'NC'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
	(b) (4)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:36
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User entered '28210'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
	(b) (4)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:46:34
User entered 'US'	System	26 Oct 2020 21:07:42

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	26 Jan 2021 18:54:22
User entered '6'	System	15 Jan 2021 17:11:01
User entered '5'	System	22 Dec 2020 20:29:38
User entered '4'	System	24 Nov 2020 19:28:52
User entered '3'	System	19 Nov 2020 14:28:16
User entered '2'	System	28 Oct 2020 13:46:45
User entered '1'	System	26 Oct 2020 21:07:42

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:51:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
User entered '26/Oct/2020 21:07'	System	26 Oct 2020 21:07:42

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:51:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:46:34
User entered 'I'	(b) (4), (b) (6)	26 Oct 2020 21:07:42

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'USA-US126-2020-MRNA-1273-P301000006'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Yes (Y)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Yes (Y)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Christina'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Kennelly'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
User closed query 'No data has been updated for address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:42:30
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:29
	(b) (4)	
Query 'No data has been updated for address fields.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 15:55:36
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
User opened query 'No data has been updated for address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:50:58
	(b) (4), (b) (6)	
User closed query 'Please add entry for each address field.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:50:58
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Query 'Please add entry for each address field.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:42:01
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User opened query 'Please add entry for each address field.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 15:54:13
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:38
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User closed query 'Kindly update the rest of this page if you are able to. Thank you.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:54:57
	(b) (4), (b) (6)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Site Address: Street](#)

Audit	User	Time (GMT)
Query 'Kindly update the rest of this page if you are able to. Thank you.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	10 Nov 2020 17:12:26
User entered '6060 Piedmont Row Drive South'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
User opened query 'Kindly update the rest of this page if you are able to. Thank you.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 19:03:36

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:33
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User entered 'Charlotte'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
	(b) (4)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:34
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User entered 'NC'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
	(b) (4)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:36
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User entered '28210'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
	(b) (4)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:46:34
User entered 'US'	System	26 Oct 2020 21:07:42

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	26 Jan 2021 18:54:22
User entered '6'	System	15 Jan 2021 17:11:01
User entered '5'	System	22 Dec 2020 20:29:38
User entered '4'	System	24 Nov 2020 19:28:52
User entered '3'	System	19 Nov 2020 14:28:16
User entered '2'	System	28 Oct 2020 13:46:45
User entered '1'	System	26 Oct 2020 21:07:42

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:51:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
User entered '28/Oct/2020 13:46'	System	28 Oct 2020 13:46:45

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:51:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:43:11
User entered 'I'	(b) (4), (b) (6)	28 Oct 2020 13:46:45

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'USA-US126-2020-MRNA-1273-P301000006'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Yes (Y)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Yes (Y)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Christina'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Kennelly'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
User closed query 'No data has been updated for address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:42:30
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:29
	(b) (4)	
Query 'No data has been updated for address fields.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 15:55:36
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
User opened query 'No data has been updated for address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:50:58
	(b) (4), (b) (6)	
User closed query 'Please add entry for each address field.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:50:58
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Query 'Please add entry for each address field.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:42:01
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User opened query 'Please add entry for each address field.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 15:54:13
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:38
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User closed query 'Kindly update the rest of this page if you are able to. Thank you.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:54:57
	(b) (4), (b) (6)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: Street

Audit	User	Time (GMT)
Query 'Kindly update the rest of this page if you are able to. Thank you.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	10 Nov 2020 17:12:26
User entered '6060 Piedmont Row Drive South'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
User opened query 'Kindly update the rest of this page if you are able to. Thank you.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 19:03:36

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:33
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User entered 'Charlotte'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
	(b) (4)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:34
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User entered 'NC'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
	(b) (4)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4)	05 Feb 2021 17:42:36
	(b) (4), (b) (6)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User entered '28210'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
	(b) (4)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:46:34
User entered 'US'	System	26 Oct 2020 21:07:42

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	26 Jan 2021 18:54:22
User entered '6'	System	15 Jan 2021 17:11:01
User entered '5'	System	22 Dec 2020 20:29:38
User entered '4'	System	24 Nov 2020 19:28:52
User entered '3'	System	19 Nov 2020 14:28:16
User entered '2'	System	28 Oct 2020 13:46:45
User entered '1'	System	26 Oct 2020 21:07:42

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:51:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:50:48
User entered '19/Nov/2020 14:28'	System	19 Nov 2020 14:28:16

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:51:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:50:48
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
User entered 'I'	(b) (4), (b) (6)	19 Nov 2020 14:28:16

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'USA-US126-2020-MRNA-1273-P301000006'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Yes (Y)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Yes (Y)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Christina'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Kennelly'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
User closed query 'No data has been updated for address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:42:30
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:29
	(b) (4)	
Query 'No data has been updated for address fields.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 15:55:36
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
User opened query 'No data has been updated for address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:50:58
	(b) (4), (b) (6)	
User closed query 'Please add entry for each address field.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:50:58
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Query 'Please add entry for each address field.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:42:01
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User opened query 'Please add entry for each address field.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 15:54:13
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:38
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User closed query 'Kindly update the rest of this page if you are able to. Thank you.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:54:57
	(b) (4), (b) (6)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Site Address: Street](#)

Audit	User	Time (GMT)
Query 'Kindly update the rest of this page if you are able to. Thank you.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	10 Nov 2020 17:12:26
User entered '6060 Piedmont Row Drive South'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
User opened query 'Kindly update the rest of this page if you are able to. Thank you.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 19:03:36

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:33
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
User entered 'Charlotte'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
	(b) (4)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:34
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User entered 'NC'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
	(b) (4)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:36
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User entered '28210'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
	(b) (4)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:46:34
User entered 'US'	System	26 Oct 2020 21:07:42

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	26 Jan 2021 18:54:22
User entered '6'	System	15 Jan 2021 17:11:01
User entered '5'	System	22 Dec 2020 20:29:38
User entered '4'	System	24 Nov 2020 19:28:52
User entered '3'	System	19 Nov 2020 14:28:16
User entered '2'	System	28 Oct 2020 13:46:45
User entered '1'	System	26 Oct 2020 21:07:42

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:51:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:50:48
User entered '24/Nov/2020 19:28'	System	24 Nov 2020 19:28:52

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:51:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:29:26
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 19:28:52

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'USA-US126-2020-MRNA-1273-P301000006'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Yes (Y)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Yes (Y)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Christina'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Kennelly'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
User closed query 'No data has been updated for address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:42:30
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:29
	(b) (4)	
Query 'No data has been updated for address fields.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 15:55:36
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
User opened query 'No data has been updated for address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:50:58
	(b) (4), (b) (6)	
User closed query 'Please add entry for each address field.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:50:58
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Query 'Please add entry for each address field.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:42:01
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User opened query 'Please add entry for each address field.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 15:54:13
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:38
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User closed query 'Kindly update the rest of this page if you are able to. Thank you.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:54:57
	(b) (4), (b) (6)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Site Address: Street](#)

Audit	User	Time (GMT)
Query 'Kindly update the rest of this page if you are able to. Thank you.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	10 Nov 2020 17:12:26
User entered '6060 Piedmont Row Drive South'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
User opened query 'Kindly update the rest of this page if you are able to. Thank you.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 19:03:36

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:33
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User entered 'Charlotte'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
	(b) (4)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:34
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User entered 'NC'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
	(b) (4)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4)	05 Feb 2021 17:42:36
	(b) (4), (b) (6)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User entered '28210'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
	(b) (4)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:46:34
User entered 'US'	System	26 Oct 2020 21:07:42

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	26 Jan 2021 18:54:22
User entered '6'	System	15 Jan 2021 17:11:01
User entered '5'	System	22 Dec 2020 20:29:38
User entered '4'	System	24 Nov 2020 19:28:52
User entered '3'	System	19 Nov 2020 14:28:16
User entered '2'	System	28 Oct 2020 13:46:45
User entered '1'	System	26 Oct 2020 21:07:42

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:51:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:54:47
User entered '22/Dec/2020 12:29'	System	22 Dec 2020 20:29:38

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:51:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 15:54:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 17:10:49
User entered 'I'	(b) (4), (b) (6)	22 Dec 2020 20:29:38

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'USA-US126-2020-MRNA-1273-P301000006'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Yes (Y)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Yes (Y)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Christina'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Kennelly'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
User closed query 'No data has been updated for address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:42:30
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:29
	(b) (4)	
Query 'No data has been updated for address fields.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 15:55:36
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
User opened query 'No data has been updated for address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:50:58
	(b) (4), (b) (6)	
User closed query 'Please add entry for each address field.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:50:58
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Query 'Please add entry for each address field.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:42:01
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User opened query 'Please add entry for each address field.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 15:54:13
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:38
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User closed query 'Kindly update the rest of this page if you are able to. Thank you.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:54:57
	(b) (4), (b) (6)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Site Address: Street](#)

Audit	User	Time (GMT)
Query 'Kindly update the rest of this page if you are able to. Thank you.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	10 Nov 2020 17:12:26
User entered '6060 Piedmont Row Drive South'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
User opened query 'Kindly update the rest of this page if you are able to. Thank you.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 19:03:36

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:33
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User entered 'Charlotte'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
	(b) (4)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:34
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User entered 'NC'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
	(b) (4)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4)	05 Feb 2021 17:42:36
	(b) (4), (b) (6)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User entered '28210'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
	(b) (4)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:46:34
User entered 'US'	System	26 Oct 2020 21:07:42

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	26 Jan 2021 18:54:22
User entered '6'	System	15 Jan 2021 17:11:01
User entered '5'	System	22 Dec 2020 20:29:38
User entered '4'	System	24 Nov 2020 19:28:52
User entered '3'	System	19 Nov 2020 14:28:16
User entered '2'	System	28 Oct 2020 13:46:45
User entered '1'	System	26 Oct 2020 21:07:42

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:51:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:55:00
User entered '15/Jan/2021 17:10'	System	15 Jan 2021 17:11:01

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:51:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 15:55:02
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6)	15 Jan 2021 17:11:01

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'USA-US126-2020-MRNA-1273-P301000006'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Yes (Y)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'No (N)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Yes (Y)'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Christina'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:07:34
User entered 'Kennelly'	System	26 Oct 2020 20:56:27

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
User closed query 'No data has been updated for address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:42:30
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:29
	(b) (4)	
Query 'No data has been updated for address fields.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Feb 2021 15:55:36
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
User opened query 'No data has been updated for address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:50:58
	(b) (4), (b) (6)	
User closed query 'Please add entry for each address field.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:50:58
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Query 'Please add entry for each address field.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:42:01
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User opened query 'Please add entry for each address field.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 15:54:13
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:38
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User closed query 'Kindly update the rest of this page if you are able to. Thank you.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:54:57
	(b) (4), (b) (6)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Site Address: Street](#)

Audit	User	Time (GMT)
Query 'Kindly update the rest of this page if you are able to. Thank you.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	10 Nov 2020 17:12:26
User entered '6060 Piedmont Row Drive South'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
User opened query 'Kindly update the rest of this page if you are able to. Thank you.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 19:03:36

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:33
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User entered 'Charlotte'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
	(b) (4)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:34
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User entered 'NC'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
	(b) (4)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:42:36
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:55:31
	(b) (4)	
Un-reviewed for Safety.	System	26 Jan 2021 18:54:22
User entered empty.	System	26 Jan 2021 18:54:22
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 18:54:08
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 14:41:54
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 15:53:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:50:48
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:28:40
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	19 Nov 2020 14:28:16
DataPoint Un-verified.	System	19 Nov 2020 14:28:16
User entered empty.	System	19 Nov 2020 14:28:16
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:28:02
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:02
	(b) (4), (b) (6)	
User entered '28210'	Kelly Woodell (b) (4)	10 Nov 2020 17:12:21
	(b) (4)	

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:11
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:46:34
User entered 'US'	System	26 Oct 2020 21:07:42

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 09:51:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	26 Jan 2021 18:54:22
User entered '6'	System	15 Jan 2021 17:11:01
User entered '5'	System	22 Dec 2020 20:29:38
User entered '4'	System	24 Nov 2020 19:28:52
User entered '3'	System	19 Nov 2020 14:28:16
User entered '2'	System	28 Oct 2020 13:46:45
User entered '1'	System	26 Oct 2020 21:07:42

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:51:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:51:15
User entered '26/Jan/2021 13:54'	System	26 Jan 2021 18:54:22

US3822043

Folder: SAE USA-US126-2020-MRNA-1273-P301000006

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:51:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 20:07:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:51:18
User entered 'I'	(b) (4), (b) (6)	26 Jan 2021 18:54:22