

US3822342 (Prod: Tryon Medical Partners, PLLC)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:57:53

All time stamps listed in this document are displayed in GMT

US3822342

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 22:13:40

Generated On: 10 Jun 2021 09:57:53

Participant ID

US3822342

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

US3822342

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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	SCRN

US3822342

Folder: Screening

Form: Demographics

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Date of Birth (MMM yyyy)	(b) (6) 1942
Age	77
Age Units	YEARS
Age (Derived)	77
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3822342

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Date of Informed Consent (<i>dd MMM yyyy</i>)	09 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" 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

US3822342

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3822342

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Were any significant conditions reported?

Yes ☒

No ☐

US3822342

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Condition	HEARING LOSS
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Start Year (derived)	1975
Stop Month and Year (derived)	
Stop Year (derived)	

US3822342

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Condition	ACNE
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)	UN UNK 1970
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	JAN 1970
Stop Year (derived)	1970

US3822342

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Condition	MITRAL VALVE PROLAPSE
Start date (dd MMM yyyy)	30 AUG 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3822342

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Condition	HEARTBURN
Start date (dd MMM yyyy)	UN UNK 1970
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 1970
Start Year (derived)	1970
Stop Month and Year (derived)	
Stop Year (derived)	

US3822342

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Condition	GERD
Start date (dd MMM yyyy)	UN UNK 1970
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 1970
Start Year (derived)	1970
Stop Month and Year (derived)	
Stop Year (derived)	

US3822342

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Condition	GALLBLADDER DISEASE
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)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

US3822342

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Condition	INGUINAL HERNIAS
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

US3822342

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Condition	URINARY INCONTINENCE
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)	

US3822342

Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Condition	PROSTATE ISSUES
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)	

US3822342

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	09 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:42 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 13:42
Height (<i>xxx.x</i>)	70 in
Weight (<i>xxx.x</i>)	191.4 lb
BMI (<i>xxx.x</i>)	27.52046 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)	

US3822342

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

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.

US3822342

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

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	

US3822342

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 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	VISIT1

US3822342

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

What was the date of randomization? (dd MMM yyyy) 09 SEP 2020

What was the participant's randomization number? 190069

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Height	ND - Not Done
Weight	ND - Not Done

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

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)	9 SEP 2020
Time of assessment (00:00-23:59)	12:33 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 12:33
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

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)	9 SEP 2020
Time of assessment (00:00-23:59)	13:58 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 13:58
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3822342

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 SEP 2020

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

US3822342

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

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) 09 SEP 2020

What was the treatment time? (00:00-23:59) 13:27 (24 HR)

Treatment Date and Time (derived) 09 SEP 2020 13:27

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

US3822342

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 SEP 2020
Collection time (00:00-23:59)	12:46 (24 HR)
Collection date and time (derived)	9 SEP 2020 12:46

US3822342

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Collection date (dd MMM yyyy)			9 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:20	9 SEP 2020 13:20
Nasopharyngeal Swab 2	No		

US3822342

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 13:59

PC Open Date & Time

09 SEP 2020 13:47

PC Close Date & Time

09 SEP 2020 16:17

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

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

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

09 SEP 2020 17:12

PC Close Date & Time

10 SEP 2020 11:59

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:53

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

96.9 °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

10 SEP 2020 16:05

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 19:40

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:53

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

96.3 °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

13 SEP 2020 00:30

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:53

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

97.4 °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 SEP 2020 20:52

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

14 SEP 2020 17:41

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:53

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

97.1 °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

15 SEP 2020 20:26

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

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

09 SEP 2020 14:00

PC Open Date & Time

09 SEP 2020 13:47

PC Close Date & Time

09 SEP 2020 16:17

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

09 SEP 2020 17:12

PC Close Date & Time

10 SEP 2020 11:59

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:53

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

10 SEP 2020 16:06

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:53

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

11 SEP 2020 19:41

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:53

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

13 SEP 2020 00:31

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:53

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

13 SEP 2020 20:52

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:53

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

14 SEP 2020 17:42

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:53

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

15 SEP 2020 20:15

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

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 ☐

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 14:01
PC Open Date & Time	09 SEP 2020 13:47
PC Close Date & Time	09 SEP 2020 16:17

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

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 ☐

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

09 SEP 2020 17:12

PC Close Date & Time

10 SEP 2020 11:59

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:53

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

59 of 2654

EAB) (1725)

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:53

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 16:08
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:53

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 2654

EAB) (1725)

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:53

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 19:42
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:53

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 2654

EAB) (1725)

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:53

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 00:32
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:53

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 2654

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:53

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 20:53
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:53

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

67 of 2654

EAB) (1725)

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:53

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 17:43
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:53

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

69 of 2654

EAB) (1725)

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:53

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 20:16
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3822342

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822342

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822342

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 21:04:37

Generated On: 10 Jun 2021 09:57:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822342

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 21:04:37

Generated On: 10 Jun 2021 09:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822342

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 21:04:37

Generated On: 10 Jun 2021 09:57:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3822342

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 21:04:37

Generated On: 10 Jun 2021 09:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822342

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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	VISIT2

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

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)	8 OCT 2020
Time of assessment (00:00-23:59)	10:38 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 10:38
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

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)	8 OCT 2020
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 11:20
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3822342

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

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.

US3822342

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

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) 08 OCT 2020

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

Treatment Date and Time (derived) 08 OCT 2020 10:56

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

What was the frequency of the study treatment dosing? ONCE

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

US3822342

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 OCT 2020
Collection time (00:00-23:59)	10:46 (24 HR)
Collection date and time (derived)	8 OCT 2020 10:46

US3822342

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Collection date (dd MMM yyyy)			8 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:50	8 OCT 2020 10:50
Nasopharyngeal Swab 2	No		

US3822342

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

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

97.9 °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

08 OCT 2020 11:22

PC Open Date & Time

08 OCT 2020 11:16

PC Close Date & Time

08 OCT 2020 13:46

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.5 °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 OCT 2020 19:26
PC Open Date & Time	08 OCT 2020 14:41
PC Close Date & Time	09 OCT 2020 11:59

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:53

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 OCT 2020 22:00

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:53

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

98.1 °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

10 OCT 2020 21:30

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:53

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

97.7 °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 OCT 2020 07:58

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:53

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 21:06

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:53

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

97.9 °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

14 OCT 2020 13:24

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

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

08 OCT 2020 11:23

PC Open Date & Time

08 OCT 2020 11:16

PC Close Date & Time

08 OCT 2020 13:46

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

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

08 OCT 2020 19:27

PC Open Date & Time

08 OCT 2020 14:41

PC Close Date & Time

09 OCT 2020 11:59

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:53

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

09 OCT 2020 22:01

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:53

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

10 OCT 2020 21:32

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:53

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

12 OCT 2020 07:58

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:53

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:53

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

13 OCT 2020 21:06

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:53

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

14 OCT 2020 13:26

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

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 ☐

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

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

No ☒

Yes ☐

PC Time stamp	08 OCT 2020 11:24
PC Open Date & Time	08 OCT 2020 11:16
PC Close Date & Time	08 OCT 2020 13:46

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

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 ☐

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

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

No ☒

Yes ☐

PC Time stamp	08 OCT 2020 19:28
PC Open Date & Time	08 OCT 2020 14:41
PC Close Date & Time	09 OCT 2020 11:59

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:53

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 ☒

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:53

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 22:02
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:53

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 2654

EAB) (1725)

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:53

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 21:32
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:53

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 ☒

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:53

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)

111 of 2654

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:53

Yes ☐

PC Time stamp

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:53

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 2654

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:53

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 21:07
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:53

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)

115 of 2654

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:53

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 13:27
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3822342

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 21:04:37

Generated On: 10 Jun 2021 09:57:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822342

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 21:04:37

Generated On: 10 Jun 2021 09:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822342

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 21:04:37

Generated On: 10 Jun 2021 09:57:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822342

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 21:04:37

Generated On: 10 Jun 2021 09:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822342

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 21:04:37

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 21:04:37

Generated On: 10 Jun 2021 09:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822342

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 NOV 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

US3822342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	2 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	10:15 (24 HR)
Vital Signs Date and Time (derived)	2 NOV 2020 10:15
Temperature (<i>xxx.x</i>)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	63 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3822342

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

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.

US3822342

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 NOV 2020
Collection time (00:00-23:59)	10:18 (24 HR)
Collection date and time (derived)	2 NOV 2020 10:18

US3822342

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 21:05:08

Generated On: 10 Jun 2021 09:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 NOV 2020 23:07:09
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3822342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

18 NOV 2020 15:28:24

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 NOV 2020 00:21:05
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	27 NOV 2020 07:35:28
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 DEC 2020 07:25:43
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 DEC 2020 08:08:34
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

18 DEC 2020 00:02:12

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	25 DEC 2020 19:00:15
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

01 JAN 2021 14:28:00

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 <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	09 JAN 2021 01:03:38
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

15 JAN 2021 23:53:50

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

22 JAN 2021 00:01:55

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 07:54:14

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 <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	09 FEB 2021 00:00:19
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 <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	12 FEB 2021 23:34:09
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

19 FEB 2021 00:39:35

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

26 FEB 2021 12:57:17

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 MAR 2021 00:48:17
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

13 MAR 2021 07:21:17

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 01:41:15

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 MAR 2021 00:29:50
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

03 APR 2021 06:44:18

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 09:42:10

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

17 APR 2021 10:51:23

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 APR 2021 11:04:31

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

30 APR 2021 08:31:36

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 <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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

DAY 250

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

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

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

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

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

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

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

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 ☐

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2021 00:01
Patient Cloud Close Date & Time	15 JUN 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 JUN 2021 00:01
Patient Cloud Close Date & Time	29 JUN 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 <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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 JUL 2021 00:01
Patient Cloud Close Date & Time	13 JUL 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2021 00:01
Patient Cloud Close Date & Time	20 JUL 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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="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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

Patient Cloud Open Date & Time	13 AUG 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 AUG 2021 00:01
Patient Cloud Close Date & Time	24 AUG 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 ☐

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 SEP 2021 00:01
Patient Cloud Close Date & Time	14 SEP 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 ☐

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

Patient Cloud Open Date & Time	15 OCT 2021 00:01
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Patient Cloud Close Date & Time	19 OCT 2021 23:59
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US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 ☐

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 NOV 2021 00:01
Patient Cloud Close Date & Time	23 NOV 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 ☐

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 DEC 2021 00:01
Patient Cloud Close Date & Time	07 DEC 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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="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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 DEC 2021 00:01
Patient Cloud Close Date & Time	21 DEC 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 ☐

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 DEC 2021 00:01
Patient Cloud Close Date & Time	28 DEC 2021 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 ☐

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 ☐

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 ☐

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 ☐

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 ☐

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 ☐

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 <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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 APR 2022 00:01
Patient Cloud Close Date & Time	12 APR 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 ☐

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 ☐

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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="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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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="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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 ☐

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 ☐

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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="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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

DAY 712

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

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

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

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

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

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

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

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

Patient Cloud Open Date & Time	26 AUG 2022 00:01
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Patient Cloud Close Date & Time	30 AUG 2022 23:59
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US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 <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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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="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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 ☐

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

Patient Cloud Open Date & Time	21 OCT 2022 00:01
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Patient Cloud Close Date & Time	25 OCT 2022 23:59
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US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 ☐

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 ☐

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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

[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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"/>

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 NOV 2022 00:01
Patient Cloud Close Date & Time	15 NOV 2022 23:59

US3822342

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:57:53

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 22:59:40

US3822342

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:24:40

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:24:40

Generated On: 10 Jun 2021 09:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822342

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822342

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822342

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

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 _____

US3822342

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822342

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Apr 2021 14:46:56

Generated On: 10 Jun 2021 09:57:53

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

Visit date (dd MMM yyyy)	20 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3822342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Apr 2021 14:46:56

Generated On: 10 Jun 2021 09:57:53

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) _____

US3822342

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Apr 2021 14:46:56

Generated On: 10 Jun 2021 09:57:53

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.

US3822342

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Apr 2021 14:46:56

Generated On: 10 Jun 2021 09:57:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 APR 2021
Collection time (00:00-23:59)	13:20 (24 HR)
Collection date and time (derived)	20 APR 2021 13:20

US3822342

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 14:46:56

Generated On: 10 Jun 2021 09:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822342

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Date of Contact	31 JAN 2021
Time of Contact	14:09
Date and Time of Contact (derived)	31 JAN 2021 14:09
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input checked="" type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	31 JAN 2021
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	1 FEB 2021
------	------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

336 of 2654

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	2 FEB 2021
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	98.8 F
-------------	--------

Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

340 of 2654

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	3 FEB 2021
------	------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

344 of 2654

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	4 FEB 2021
------	------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

348 of 2654

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Date of Visit	2 FEB 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	2 FEB 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3822342

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3822342

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3822342

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 FEB 2021
Time of assessment (00:00-23:59)	13:32 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 13:32
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	24 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3822342

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 FEB 2021

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

US3822342

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

2 FEB 2021

US3822342

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 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

US3822342

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

Form: Unblinding

Data signed: (b) (4) 23 Apr 2021 14:46:56

Generated On: 10 Jun 2021 09:57:53

Date of updated informed consent (<i>dd MMM yyyy</i>)	05 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	04 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3822342

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Height	70 in
Weight	196.0 lb
BMI (xxx.x)	28.18187

US3822342

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Height	70 in
Weight	196.0 lb
BMI (xxx.x)	28.18187
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)	5 JAN 2021
Time of assessment (00:00-23:59)	11:19 (24 HR)
Vital Signs Date and Time (derived)	5 JAN 2021 11:19
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3822342

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Height	70 in
Weight	196.0 lb
BMI (xxx.x)	28.18187
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)	5 JAN 2021
Time of assessment (00:00-23:59)	12:41 (24 HR)
Vital Signs Date and Time (derived)	5 JAN 2021 12:41
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3822342

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

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 JAN 2021

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

US3822342

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

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 5 JAN 2021

What was the treatment time? (00:00-23:59) 12:03 (24 HR)

Treatment Date and Time (derived) 5 JAN 2021 12:03

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

US3822342

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

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

Collection date (dd MMM yyyy)	5 JAN 2021
-------------------------------	------------

Collection time (00:00-23:59)	11:24 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	5 JAN 2021 11:24
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US3822342

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 JAN 2021
Collection time (00:00 - 23:59)	11:30
Collection Date and Time (derived)	5 JAN 2021 11:30

US3822342

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

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822342

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822342

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

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)	25 FEB 2021
Time of assessment (00:00-23:59)	10:19 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 10:19
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

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)	25 FEB 2021
Time of assessment (00:00-23:59)	11:10 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 11:10
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)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3822342

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

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.

US3822342

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 25 FEB 2021

What was the treatment time? (00:00-23:59) 10:40 (24 HR)

Treatment Date and Time (derived) 25 FEB 2021 10:40

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

US3822342

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822342

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822342

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822342

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3822342

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

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) _____

US3822342

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

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.

US3822342

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 MAR 2021
Collection time (00:00-23:59)	13:28 (24 HR)
Collection date and time (derived)	17 MAR 2021 13:28

US3822342

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 19:02:58

Generated On: 10 Jun 2021 09:57:53

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 12:57:10

Generated On: 10 Jun 2021 09:57:53

AEID

Adverse event

DIZZY AND SWEATY WITH
LOW BLOOD PRESSURE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

9 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

9 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

383 of 2654

EAB) (1725)

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 12:57:10

Generated On: 10 Jun 2021 09:57:53

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 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 type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 12:57:10

Generated On: 10 Jun 2021 09:57:53

AEID	USA-US126-2021-MRNA-1273-P30 1000004
Adverse event	RIGHT PLEURAL EFFUSION
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)	05 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	08 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	05 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	07 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

385 of 2654

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 12:57:10

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 12:57:10

Generated On: 10 Jun 2021 09:57:53

THE SUBJECT WAS TESTED FOR
COVID-19 THROUGH THE TRIAL
AND FOUND TO BE NEGATIVE.
HE WAS HAVING DIFFICULTY
BREATHING AND PRESENTED
TO THE EMERGENCY ROOM ON
05FEB2021. HE WAS FOUND TO
HAVE A PLEURAL EFFUSION
WHICH WAS DRAINED. THE
SUBJECT WAS STARTED ON
DOXYCYCLINE AND
DISCHARGED ON 07FEB2021.

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

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 12:57:10

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 12:57:10

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 12:57:10

Generated On: 10 Jun 2021 09:57:53

AEID

Adverse event

WORSENING OF
HYPERTENSION

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)

15 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

15 DEC 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

390 of 2654

EAB) (1725)

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 12:57:10

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

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

Yes ☒

No ☐

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

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 22:13:40

Generated On: 10 Jun 2021 09:57:53

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HCL

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)

393 of 2654

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 22:13:40

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 22:13:40

Generated On: 10 Jun 2021 09:57:53

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

395 of 2654

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 22:13:40

Generated On: 10 Jun 2021 09:57:53

	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 1970
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"/>

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 22:13:40

Generated On: 10 Jun 2021 09:57:53

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HTN

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)

397 of 2654

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 22:13:40

Generated On: 10 Jun 2021 09:57:53

	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 2005	
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"/>

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 22:13:40

Generated On: 10 Jun 2021 09:57:53

Name of Medication ASA

Prophylaxis Yes ☒
No ☐

Indication CARDIAC SUPPLEMENT -
HEART ISSUES BEING
MONITORED

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

399 of 2654

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 22:13:40

Generated On: 10 Jun 2021 09:57:53

	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 2014	
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"/>

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 22:13:40

Generated On: 10 Jun 2021 09:57:53

Name of Medication ATENDRONATE

Prophylaxis Yes ☐
No ☒

Indication OSTEOGENESIS IMPERFECTA

Dose per administration 70

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)

401 of 2654

EAB) (1725)

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 22:13:40

Generated On: 10 Jun 2021 09:57:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 FEB 2019
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 22:13:40

Generated On: 10 Jun 2021 09:57:53

Name of Medication MIRABEGRON

Prophylaxis Yes ☐
No ☒

Indication OVERACTIVE BLADDER -
URINARY INCONTINENCE

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

403 of 2654

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 22:13:40

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 22:13:40

Generated On: 10 Jun 2021 09:57:53

Name of Medication HEP B

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)

405 of 2654

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 22:13:40

Generated On: 10 Jun 2021 09:57:53

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 SEP 2011
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		16 SEP 2011
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"/>

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 22:13:40

Generated On: 10 Jun 2021 09:57:53

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 ☐

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 22:13:40

Generated On: 10 Jun 2021 09:57:53

	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)	21 APR 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		21 APR 2014
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"/>

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 22:13:40

Generated On: 10 Jun 2021 09:57:53

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)

409 of 2654

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 22:13:40

Generated On: 10 Jun 2021 09:57:53

	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)	23 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		23 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 Apr 2021 22:13:40

Generated On: 10 Jun 2021 09:57:53

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)

411 of 2654

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 Apr 2021 22:13:40

Generated On: 10 Jun 2021 09:57:53

	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)		22 JUN 2009
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		22 JUN 2009
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"/>

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 22:13:40

Generated On: 10 Jun 2021 09:57:53

Name of Medication TROSPiUM - WORSENING OF
OVERACTIVE BLADDER

Prophylaxis Yes ☐
No ☒

Indication URINARY INCONTINENCE

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

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

413 of 2654

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 22:13:40

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 02 Apr 2021 22:13:40

Generated On: 10 Jun 2021 09:57:53

Name of Medication DOXYCYCLINE HYCLATE

Prophylaxis Yes ☐
No ☒

Indication RIGHT PLEURAL EFFUSION

Dose per administration 110

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)

415 of 2654

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 02 Apr 2021 22:13:40

Generated On: 10 Jun 2021 09:57:53

	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)		07 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 Apr 2021 22:13:40

Generated On: 10 Jun 2021 09:57:53

Name of Medication AMLODIPINE BESYLATE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

417 of 2654

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 Apr 2021 22:13:40

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3822342

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 22:13:41

Generated On: 10 Jun 2021 09:57:53

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
07 FEB 2021	ULTRASOUND GUIDED RIGHT THORACENTESIS	Adverse Event	
05 FEB 2021	CHEST X-RAY PA AND LATERAL	Diagnostic	
05 FEB 2021	CT CHEST WITH IV CONTRAST	Diagnostic	
06 FEB 2021	CHEST X-RAY	Diagnostic	
22 MAR 2021	CHEST X-RAY	Adverse Event	

US3822342

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:57:53

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

US3822342

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:57:53

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 ☐

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 30 Apr 2021 20:01:39

Generated On: 10 Jun 2021 09:57:53

SAEID	USA-US126-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 20:01:39

Generated On: 10 Jun 2021 09:57:53

SAEID	USA-US126-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	09/FEB/2021 12:45
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

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Apr 2021 20:01:39

Generated On: 10 Jun 2021 09:57:53

SAEID	USA-US126-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	22/FEB/2021 14:51
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

US3822342

Folder: SAE-USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 30 Apr 2021 20:01:39

Generated On: 10 Jun 2021 09:57:53

SAEID	USA-US126-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	25/MAR/2021 11:20
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3822342

Folder: SAE-USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 30 Apr 2021 20:01:39

Generated On: 10 Jun 2021 09:57:53

SAEID	USA-US126-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	09/APR/2021 15:21
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

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) 30 Apr 2021 20:01:39

Generated On: 10 Jun 2021 09:57:53

SAEID	USA-US126-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	22/APR/2021 10:49
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

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form (6)

Data signed: (b) (4) 30 Apr 2021 20:01:39

Generated On: 10 Jun 2021 09:57:53

SAEID	USA-US126-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	30/APR/2021 13:20
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3822342 (Prod: Tryon Medical Partners, PLLC)

US3822342

Form: Participant Creation

Generated On: 10 Jun 2021 09:57:53

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:48:23
User entered 'US3822342'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 17:39:54

US3822342

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:24:34

US3822342

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	(b) (4)	
	System	16 Nov 2020 18:55:36
User entered '09 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:55:36
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	09 Sep 2020 17:39:09
User entered '01 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 17:39:56

US3822342

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

[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 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:24:34

US3822342

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'SCRN'	System	30 Sep 2020 15:24:34

US3822342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:53

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered (b) (6) 1942'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 17:39:57

US3822342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:53

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	23 Nov 2020 12:59:36
User entered '77' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 12:59:36
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	09 Sep 2020 17:39:09
User entered '78'	Kelly Woodell (b) (4)	02 Sep 2020 23:51:05

US3822342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:53

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'YEARS'	System	02 Sep 2020 23:51:05

US3822342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:53

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered '77'	System	09 Sep 2020 17:39:09

US3822342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:53

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Male (M)'	Kelly Woodell (b) (4)	02 Sep 2020 23:51:05

US3822342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:53

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kelly Woodell (b) (4)	02 Sep 2020 23:51:05

US3822342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:53

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'I'	Kelly Woodell (b) (4)	02 Sep 2020 23:51:05

US3822342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:53

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	Kelly Woodell (b) (4)	02 Sep 2020 23:51:05

US3822342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:53

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	Kelly Woodell (b) (4)	02 Sep 2020 23:51:05

US3822342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:53

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	Kelly Woodell (b) (4)	02 Sep 2020 23:51:05

US3822342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:53

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	Kelly Woodell (b) (4)	02 Sep 2020 23:51:05

US3822342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	Kelly Woodell (b) (4)	02 Sep 2020 23:51:05

US3822342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:53

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	Kelly Woodell (b) (4)	02 Sep 2020 23:51:05

US3822342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:53

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	Kelly Woodell (b) (4)	02 Sep 2020 23:51:05

US3822342

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:57:53

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	Kelly Woodell (b) (4)	02 Sep 2020 23:51:05

US3822342

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:57:53

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '09 Sep 2020'	Kelly Woodell (b) (4)	09 Sep 2020 17:39:09

US3822342

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'Sep 2020'	System	09 Sep 2020 17:39:09

US3822342

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered '2020'	System	09 Sep 2020 17:39:09

US3822342

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:57:53

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Amendment 3 (3)'	Kelly Woodell (b) (4)	09 Sep 2020 17:39:09

US3822342

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	09 Sep 2020 17:39:09

US3822342

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	Kelly Woodell (b) (4)	09 Sep 2020 17:39:09

US3822342

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:57:53

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	Kelly Woodell (b) (4)	09 Sep 2020 17:39:09

US3822342

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:57:53

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'No (N)'	Kelly Woodell (b) (4)	09 Sep 2020 17:39:09

US3822342

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:57:53

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 17:39:56

US3822342

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:57:53

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'I'	System	09 Sep 2020 17:39:26

US3822342

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	09 Sep 2020 17:39:26

US3822342

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:57:53

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:24:42

US3822342

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:57:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness, LLT: Hearing loss - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:27:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:27:02
Data point term sent to Coder	System	30 Sep 2020 15:26:15
User entered 'Hearing loss'	(b) (4), (b) (6)	30 Sep 2020 15:25:17

US3822342

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'UN UNK 1975'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:25:17

US3822342

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:25:17

US3822342

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:57:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:25:17

US3822342

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:25:17

US3822342

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:57:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:25:17

US3822342

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'Jan 1975'	System	30 Sep 2020 15:25:17

US3822342

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered '1975'	System	30 Sep 2020 15:25:17

US3822342

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:25:17

US3822342

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:25:17

US3822342

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:57:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User coded data point as SOC: Eye disorders, HLGT: Ocular structural change, deposit and degeneration NEC, HLT: Retinal structural change, deposit and degeneration, PT: Macular degeneration, LLT: Macular degeneration - version MedDRA\\23.0.	(b) (4)	30 Sep 2020 15:27:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:27:02
Data point term sent to Coder	(b) (4)	30 Sep 2020 15:26:15
User entered 'Macular degeneration'	System	30 Sep 2020 15:25:38
	(b) (4), (b) (6)	

US3822342

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'UN UNK 2005'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:25:38

US3822342

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:25:38

US3822342

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:57:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:25:38

US3822342

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:25:38

US3822342

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:57:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:25:38

US3822342

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'Jan 2005'	System	30 Sep 2020 15:25:38

US3822342

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered '2005'	System	30 Sep 2020 15:25:38

US3822342

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:25:38

US3822342

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:25:38

US3822342

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:57:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:27:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:27:03
Data point term sent to Coder	System	30 Sep 2020 15:26:15
User entered 'Sleep apnea'	(b) (4), (b) (6)	30 Sep 2020 15:25:49

US3822342

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'UN UNK 2019'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:25:49

US3822342

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:25:49

US3822342

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:57:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:25:49

US3822342

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:25:49

US3822342

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:57:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:25:49

US3822342

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'Jan 2019'	System	30 Sep 2020 15:25:49

US3822342

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered '2019'	System	30 Sep 2020 15:25:49

US3822342

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:25:49

US3822342

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:25:49

US3822342

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:57:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Skin cancer, LLT: Skin cancer - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	08 Oct 2020 18:22:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 18:22:57
Data point term sent to Coder	System	30 Sep 2020 15:26:16
User entered 'Skin cancer on back'	(b) (4), (b) (6)	30 Sep 2020 15:26:01

US3822342

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'UN UNK 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:26:01

US3822342

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:26:01

US3822342

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:57:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:26:01

US3822342

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:26:01

US3822342

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:57:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:26:01

US3822342

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'Jan 2020'	System	30 Sep 2020 15:26:01

US3822342

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered '2020'	System	30 Sep 2020 15:26:01

US3822342

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:26:01

US3822342

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:26:01

US3822342

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:57:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Acnes, PT: Acne, LLT: Acne - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:28:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:28:49
Data point term sent to Coder	System	30 Sep 2020 15:27:16
User entered 'Acne'	(b) (4), (b) (6)	30 Sep 2020 15:26:29

US3822342

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:26:29

US3822342

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:26:29

US3822342

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:57:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:26:29

US3822342

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'UN UNK 1970'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:26:29

US3822342

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:57:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:26:29

US3822342

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:26:29

US3822342

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:26:29

US3822342

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'Jan 1970'	System	30 Sep 2020 15:26:29

US3822342

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered '1970'	System	30 Sep 2020 15:26:29

US3822342

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:57:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User closed query 'Per MM, please clarify the MH term.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:49:14
' (Site from DM).		
Query 'Per MM, please clarify the MH term.	(b) (4), (b) (6)	14 Dec 2020 13:56:04
' answered with 'patient taking rosuvastatin for HCL' (Site from DM).		
User opened query 'Per MM, please clarify the MH term.	(b) (4), (b) (6)	14 Dec 2020 10:46:58
' (Site from DM).		
User coded data point as SOC: Investigations, HLGT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:28:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:28:49
Data point term sent to Coder	System	30 Sep 2020 15:27:17
User entered 'High cholesterol'	(b) (4), (b) (6)	30 Sep 2020 15:26:42

US3822342

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:26:42

US3822342

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:26:42

US3822342

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:57:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:26:42

US3822342

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:26:42

US3822342

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:57:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:26:42

US3822342

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'Jan 2010'	System	30 Sep 2020 15:26:42

US3822342

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered '2010'	System	30 Sep 2020 15:26:42

US3822342

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:26:42

US3822342

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:26:42

US3822342

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:57:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User closed query 'Per MM, please clarify the MH term.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:49:19
' (Site from DM).		
Query 'Per MM, please clarify the MH term.	(b) (4), (b) (6)	14 Dec 2020 13:56:32
' answered with 'patient reported high triglycerides on med hx sheet' (Site from DM).		
User opened query 'Per MM, please clarify the MH term.	(b) (4), (b) (6)	14 Dec 2020 10:47:13
' (Site from DM).		
User coded data point as SOC: Investigations, HLGT: Lipid analyses, HLT: Triglyceride analyses, PT: Blood triglycerides increased, LLT: Triglycerides high - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:28:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:28:49
Data point term sent to Coder	System	30 Sep 2020 15:27:19
User entered 'High triglycerides'	(b) (4), (b) (6)	30 Sep 2020 15:27:00

US3822342

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:27:00

US3822342

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:27:00

US3822342

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:57:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:27:00

US3822342

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:27:00

US3822342

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:57:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:27:00

US3822342

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'Jan 2010'	System	30 Sep 2020 15:27:00

US3822342

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered '2010'	System	30 Sep 2020 15:27:00

US3822342

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:27:00

US3822342

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:27:00

US3822342

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:57:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:28:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:28:49
Data point term sent to Coder	System	30 Sep 2020 15:27:19
User entered 'Hypertension'	(b) (4), (b) (6)	30 Sep 2020 15:27:14

US3822342

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'UN UNK 2005'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:27:14

US3822342

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:27:14

US3822342

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:57:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:27:14

US3822342

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:27:14

US3822342

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:57:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:27:14

US3822342

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'Jan 2005'	System	30 Sep 2020 15:27:14

US3822342

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered '2005'	System	30 Sep 2020 15:27:14

US3822342

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:27:14

US3822342

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:27:14

US3822342

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:57:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User coded data point as SOC: Cardiac disorders, HLT: Myocardial disorders, HLT: Myocardial disorders NEC, PT: Cardiomegaly, LLT: Heart enlarged - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:28:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:28:50
Data point term sent to Coder	System	30 Sep 2020 15:28:20
User entered 'Enlarged heart'	(b) (4), (b) (6)	30 Sep 2020 15:27:26

US3822342

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'UN Aug 2019'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:27:26

US3822342

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:27:26

US3822342

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:57:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:27:26

US3822342

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:27:26

US3822342

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:57:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:27:26

US3822342

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'Aug 2019'	System	30 Sep 2020 15:27:26

US3822342

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered '2019'	System	30 Sep 2020 15:27:26

US3822342

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:27:26

US3822342

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:27:26

US3822342

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:57:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Ankle edema - version MedDRA\23.0.	Coder Import (b) (4)	14 Dec 2020 12:25:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Dec 2020 12:25:01
Data point term sent to Coder	System	02 Dec 2020 20:47:38
User closed query 'For coding purposes, please specify location of the EDEMA and update the term with your response.' (Site from System).	System	02 Dec 2020 20:46:45
Query 'For coding purposes, please specify location of the EDEMA and update the term with your response.' answered with 'UPDATED' (Site from System).	(b) (4), (b) (6)	02 Dec 2020 20:46:45
Coding entries removed.	(b) (4), (b) (6)	02 Dec 2020 20:46:39
User entered 'EDEMA OF THE ANKLES' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 20:46:39
User opened query 'For coding purposes, please specify location of the EDEMA and update the term with your response.' (Site from System).	Coder Import (b) (4)	16 Nov 2020 21:16:58
Query 'Per DM CLR: Please review and update AE term to reflect specific body location of edema. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	06 Nov 2020 14:29:52
' canceled (Site from DM).		
User opened query 'Per DM CLR: Please review and update AE term to reflect specific body location of edema. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	29 Oct 2020 18:43:57
' (Site from DM).		

US3822342

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:57:53

Condition

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema, LLT: Edema - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:28:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:28:50
Data point term sent to Coder	System	30 Sep 2020 15:28:20
User entered 'Edema'	(b) (4), (b) (6)	30 Sep 2020 15:27:37

US3822342

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'UN Jul 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:27:37

US3822342

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:27:37

US3822342

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:57:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:27:37

US3822342

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:27:37

US3822342

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:57:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:27:37

US3822342

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'Jul 2020'	System	30 Sep 2020 15:27:37

US3822342

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered '2020'	System	30 Sep 2020 15:27:37

US3822342

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:27:37

US3822342

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:27:37

US3822342

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:57:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User coded data point as SOC: Cardiac disorders, HLT: Cardiac valve disorders, HLT: Mitral valvular disorders, PT: Mitral valve prolapse, LLT: Mitral valve prolapse - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:28:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:28:50
Data point term sent to Coder	System	30 Sep 2020 15:28:21
User entered 'Mitral Valve Prolapse'	(b) (4), (b) (6)	30 Sep 2020 15:28:00

US3822342

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '30 Aug 2019'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:28:00

US3822342

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:28:00

US3822342

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:57:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:28:00

US3822342

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:28:00

US3822342

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:57:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:28:00

US3822342

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'Aug 2019'	System	30 Sep 2020 15:28:00

US3822342

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered '2019'	System	30 Sep 2020 15:28:00

US3822342

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:28:00

US3822342

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:28:00

US3822342

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:57:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:28:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:28:50
Data point term sent to Coder	System	30 Sep 2020 15:28:22
User entered 'Heartburn'	(b) (4), (b) (6)	30 Sep 2020 15:28:11

US3822342

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'UN UNK 1970'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:28:11

US3822342

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:28:11

US3822342

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:57:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:28:11

US3822342

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:28:11

US3822342

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:57:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:28:11

US3822342

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'Jan 1970'	System	30 Sep 2020 15:28:11

US3822342

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered '1970'	System	30 Sep 2020 15:28:11

US3822342

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:28:11

US3822342

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:28:11

US3822342

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:57:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	30 Sep 2020 15:29:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:29:47
Data point term sent to Coder	System	30 Sep 2020 15:29:23
User entered 'GERD'	(b) (4), (b) (6)	30 Sep 2020 15:28:23

US3822342

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'UN UNK 1970'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:28:23

US3822342

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:28:23

US3822342

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:57:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:28:23

US3822342

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:28:23

US3822342

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:57:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:28:23

US3822342

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'Jan 1970'	System	30 Sep 2020 15:28:23

US3822342

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered '1970'	System	30 Sep 2020 15:28:23

US3822342

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:28:23

US3822342

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:28:23

US3822342

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:57:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Gallbladder disorders NEC, PT: Gallbladder disorder, LLT: Gallbladder disease - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:29:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:29:47
Data point term sent to Coder	System	30 Sep 2020 15:29:23
User entered 'Gallbladder Disease'	(b) (4), (b) (6)	30 Sep 2020 15:28:39

US3822342

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:28:39

US3822342

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:28:39

US3822342

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:57:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:28:39

US3822342

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'UN UNK 2019'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:28:39

US3822342

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:57:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:28:39

US3822342

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:28:39

US3822342

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:28:39

US3822342

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'Jan 2019'	System	30 Sep 2020 15:28:39

US3822342

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered '2019'	System	30 Sep 2020 15:28:39

US3822342

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:57:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User closed query 'Per MM, please specify the type of hernia ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 05:58:39
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Inguinal hernia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 22:18:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 22:18:28
Data point term sent to Coder	System	27 Oct 2020 22:17:29
Query 'Per MM, please specify the type of hernia ' answered with 'updated ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	27 Oct 2020 22:17:19
Coding entries removed.	Krishna Shah (b) (4) (b) (4)	27 Oct 2020 22:17:14
User entered 'Inguinal HERNIAS' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	27 Oct 2020 22:17:14
User opened query 'Per MM, please specify the type of hernia ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:43:42
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Hernias NEC, PT: Hernia, LLT: Hernia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:29:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:29:47
Data point term sent to Coder	System	30 Sep 2020 15:29:22
User entered 'Hernias'	(b) (4), (b) (6)	30 Sep 2020 15:28:55

US3822342

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'UN UNK 2005'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:28:55

US3822342

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:28:55

US3822342

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:57:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:28:55

US3822342

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'UN UNK 2005'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:28:55

US3822342

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:57:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:28:55

US3822342

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'Jan 2005'	System	30 Sep 2020 15:28:55

US3822342

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered '2005'	System	30 Sep 2020 15:28:55

US3822342

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'Jan 2005'	System	30 Sep 2020 15:28:55

US3822342

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered '2005'	System	30 Sep 2020 15:28:55

US3822342

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:57:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary incontinence, LLT: Urinary incontinence - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:29:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:29:47
Data point term sent to Coder	System	30 Sep 2020 15:29:22
User entered 'Urinary Incontinence'	(b) (4), (b) (6)	30 Sep 2020 15:29:13

US3822342

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:29:13

US3822342

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:29:13

US3822342

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:57:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:29:13

US3822342

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:29:13

US3822342

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:57:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:29:13

US3822342

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'Jan 2017'	System	30 Sep 2020 15:29:13

US3822342

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered '2017'	System	30 Sep 2020 15:29:13

US3822342

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:29:13

US3822342

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:29:13

US3822342

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:57:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteopenia, LLT: Osteopenia - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:30:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:30:52
Data point term sent to Coder	System	30 Sep 2020 15:30:24
User entered 'Osteopenia'	(b) (4), (b) (6)	30 Sep 2020 15:29:25

US3822342

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'UN Feb 2019'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:29:25

US3822342

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:29:25

US3822342

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:57:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Sep 2020 15:29:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 15:29:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 15:29:42
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 15:29:25
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:29:25

US3822342

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:29:25

US3822342

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:57:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:29:25

US3822342

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'Feb 2019'	System	30 Sep 2020 15:29:25

US3822342

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered '2019'	System	30 Sep 2020 15:29:25

US3822342

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:29:25

US3822342

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:29:25

US3822342

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:57:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatic disorder, LLT: Prostatic disorder - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:30:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:30:51
Data point term sent to Coder	System	30 Sep 2020 15:30:24
User entered 'Prostate issues'	(b) (4), (b) (6)	30 Sep 2020 15:29:37

US3822342

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:29:37

US3822342

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:29:37

US3822342

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:57:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:29:37

US3822342

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:29:37

US3822342

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:57:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:29:37

US3822342

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'Jan 2017'	System	30 Sep 2020 15:29:37

US3822342

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered '2017'	System	30 Sep 2020 15:29:37

US3822342

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:29:37

US3822342

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered empty.	System	30 Sep 2020 15:29:37

US3822342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User closed query 'Per CDM: Please enter data for "Were vital signs assessed?", "Date of assessment" and "Time of assessment". If not done please explain further. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 08:06:53
User closed query 'Response to were vital signs assessed is No, but height or weight is provided. Please correct.' (Site from System).	System	16 Nov 2020 18:57:59
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	16 Nov 2020 18:57:59
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:57:59
User opened query 'Response to were vital signs assessed is No, but height or weight is provided. Please correct.' (Site from System).	System	16 Nov 2020 18:57:32
Query 'Per CDM: Please enter data for "Were vital signs assessed?", "Date of assessment" and "Time of assessment". If not done please explain further. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 18:57:26
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	16 Nov 2020 18:57:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:57:19
User opened query 'Per CDM: Please enter data for "Were vital signs assessed?", "Date of assessment" and "Time of assessment". If not done please explain further. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 12:14:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 12:14:47
Query 'Data is required. Please complete.' answered with 'ND' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 15:33:34
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 15:33:29
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:33:29

US3822342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	16 Nov 2020 19:00:43
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	16 Nov 2020 19:00:43
User closed query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	16 Nov 2020 19:00:43
User entered '09 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 19:00:43
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	16 Nov 2020 19:00:01
User opened query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	16 Nov 2020 19:00:01
User entered '01 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 19:00:01
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Nov 2020 18:58:11
User entered '9 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:58:11
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Nov 2020 18:57:59
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:33:29

US3822342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	16 Nov 2020 18:58:11
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	16 Nov 2020 18:58:11
User entered '13:42' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:58:11
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Nov 2020 18:57:59
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:33:29

US3822342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered '09 Sep 2020 13:42'	System	16 Nov 2020 19:00:43
User entered '01 Sep 2020 13:42'	System	16 Nov 2020 19:00:01
User entered '9 Sep 2020 13:42'	System	16 Nov 2020 18:58:11
User entered empty.	System	30 Sep 2020 15:33:29

US3822342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '70' in reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:57:59
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:57:32
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:57:19
User entered '70' in	(b) (4), (b) (6)	30 Sep 2020 15:33:29
DataPoint set to visible.	System	09 Sep 2020 17:39:26

US3822342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '191.4' lb reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:57:59
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:57:32
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:57:19
User entered '191.4' lb	(b) (4), (b) (6)	30 Sep 2020 15:33:29
DataPoint set to visible.	System	09 Sep 2020 17:39:26

US3822342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered '27.52046'	System	16 Nov 2020 18:57:59
User entered empty.	System	16 Nov 2020 18:57:19
User entered '27.52046'	System	30 Sep 2020 15:33:29
DataPoint set to visible.	System	09 Sep 2020 17:39:26

US3822342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'kg/m2'	System	16 Nov 2020 18:57:59
User entered empty.	System	16 Nov 2020 18:57:19
User entered 'kg/m2'	System	30 Sep 2020 15:33:29
DataPoint set to visible.	System	09 Sep 2020 17:39:26

US3822342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:33:29

US3822342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:33:29

US3822342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:33:29

US3822342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:33:29

US3822342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'bpm'	System	30 Sep 2020 15:33:29

US3822342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:33:29

US3822342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'breaths/min'	System	30 Sep 2020 15:33:29

US3822342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:33:29

US3822342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'mmHg'	System	30 Sep 2020 15:33:29

US3822342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:33:29

US3822342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User entered 'mmHg'	System	30 Sep 2020 15:33:29

US3822342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02

US3822342

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02

US3822342

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:57:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:33:56

US3822342

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:57:53

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:33:56

US3822342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:53

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:34:29

US3822342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:53

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:34:29

US3822342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:53

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)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:34:29

US3822342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:53

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)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:34:29

US3822342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:53

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:34:29

US3822342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:53

[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)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:34:29

US3822342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:53

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)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:34:29

US3822342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:53

[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)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:34:29

US3822342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:53

[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)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:34:29

US3822342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:53

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)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:34:29

US3822342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:53

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)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:34:29

US3822342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:53

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:34:29

US3822342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:34:29

US3822342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:53

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:34:29

US3822342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:53

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:34:29

US3822342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:53

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)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:34:29

US3822342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:53

[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)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:34:29

US3822342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:53

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)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:34:29

US3822342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:53

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:34:29

US3822342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:53

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:34:29

US3822342

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:57:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:52:02
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:34:29

US3822342

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:34:52

US3822342

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:34:52

US3822342

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:34:52

US3822342

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'VISIT1'	System	30 Sep 2020 15:34:52

US3822342

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '09 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 16:29:42

US3822342

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:57:53

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '190069'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 16:29:42

US3822342

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:57:53

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 16:29:42

US3822342

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:57:53

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:35:02

US3822342

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:57:53

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:35:02

US3822342

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:57:53

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:35:02

US3822342

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:57:53

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:35:02

US3822342

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:57:53

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:35:02

US3822342

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:57:53

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:35:02
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:59:04
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:59:03

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:57:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User closed query 'Per CDM re-query: Site response is noted. The Screening Date has been recently updated to 09Sep which is now the same date of the Visit 1 Day 1. Therefore, please remove the HEIGHT and WEIGHT and enter "ND-Not Done". Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 06:13:25
Query 'Per CDM re-query: Site response is noted. The Screening Date has been recently updated to 09Sep which is now the same date of the Visit 1 Day 1. Therefore, please remove the HEIGHT and WEIGHT and enter "ND-Not Done". Thank you.'	(b) (4), (b) (6)	02 Dec 2020 20:47:12
answered with 'UPDATED' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 20:47:07
User opened query 'Per CDM re-query: Site response is noted. The Screening Date has been recently updated to 09Sep which is now the same date of the Visit 1 Day 1. Therefore, please remove the HEIGHT and WEIGHT and enter "ND-Not Done". Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 14:34:12
User closed query ' Per CDM: Screening date is 01-sep-2020 and Visit day 1 is 09-sep-2020 which are not same. Hence Please update the missing data for Height and Weight for the 09-sep-2020 on this form. Else Clarify.	(b) (4), (b) (6)	23 Nov 2020 14:34:12
' (Site from DM).		
Query ' Per CDM: Screening date is 01-sep-2020 and Visit day 1 is 09-sep-2020 which are not same. Hence Please update the missing data for Height and Weight for the 09-sep-2020 on this form. Else Clarify.	(b) (4), (b) (6)	16 Nov 2020 19:00:55
' answered with 'UPDATED' (Site from DM).		
User entered '70' in reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:59:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:58:50

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:57:53

Height

Audit	User	Time (GMT)
User opened query ' Per CDM: Screening date is 01-sep-2020 and Visit day 1 is 09-sep-2020 which are not same. Hence Please update the missing data for Height and Weight for the 09-sep-2020 on this form. Else Clarify. ' (Site from DM). User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Oct 2020 12:25:58
	(b) (4), (b) (6) (b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:57:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 20:47:07
User entered '191.4' lb reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:59:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:58:50
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:57:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User closed query 'Per CDM re-query: Site response is noted. The Screening Date has been recently updated to 09Sep which is now the same date of the Visit 1 Day 1. Therefore, please remove the HEIGHT and WEIGHT and enter "ND-Not Done". Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 06:13:25
Query 'Per CDM re-query: Site response is noted. The Screening Date has been recently updated to 09Sep which is now the same date of the Visit 1 Day 1. Therefore, please remove the HEIGHT and WEIGHT and enter "ND-Not Done". Thank you.'	(b) (4), (b) (6)	02 Dec 2020 20:47:12
answered with 'UPDATED' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 20:47:07
User opened query 'Per CDM re-query: Site response is noted. The Screening Date has been recently updated to 09Sep which is now the same date of the Visit 1 Day 1. Therefore, please remove the HEIGHT and WEIGHT and enter "ND-Not Done". Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 14:34:12
User closed query ' Per CDM: Screening date is 01-sep-2020 and Visit day 1 is 09-sep-2020 which are not same. Hence Please update the missing data for Height and Weight for the 09-sep-2020 on this form. Else Clarify.	(b) (4), (b) (6)	23 Nov 2020 14:34:12
' (Site from DM).		
Query ' Per CDM: Screening date is 01-sep-2020 and Visit day 1 is 09-sep-2020 which are not same. Hence Please update the missing data for Height and Weight for the 09-sep-2020 on this form. Else Clarify.	(b) (4), (b) (6)	16 Nov 2020 19:00:55
' answered with 'UPDATED' (Site from DM).		
User entered '70' in reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:59:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:58:50

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:57:53

Height

Audit	User	Time (GMT)
User opened query ' Per CDM: Screening date is 01-sep-2020 and Visit day 1 is 09-sep-2020 which are not same. Hence Please update the missing data for Height and Weight for the 09-sep-2020 on this form. Else Clarify. ' (Site from DM). User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Oct 2020 12:25:58
	(b) (4), (b) (6) (b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:57:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 20:47:07
User entered '191.4' lb reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:59:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:58:50
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User closed query 'Per CDM RQ: The Vital signs Post dose Time of Assessment 12:33 is prior to the Treatment time on the Exposure CRF 13:27. Please review and update appropriately. Thankyou.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 10:30:18
User entered '12:33' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:03:09
Query 'Per CDM RQ: The Vital signs Post dose Time of Assessment 12:33 is prior to the Treatment time on the Exposure CRF 13:27. Please review and update appropriately. Thankyou.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 13:01:47
User entered '11:35' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:01:41
User opened query 'Per CDM RQ: The Vital signs Post dose Time of Assessment 12:33 is prior to the Treatment time on the Exposure CRF 13:27. Please review and update appropriately. Thankyou.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 07:13:33
User closed query 'Per CDM: The treatment time on the Exposure CRF is 13:27 and the Vital Signs Post Dose Time of Assessment is 13:38 which has 11 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. 'Please clarify' the post dosing time of assessment and update as needed.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 07:13:33
Query 'Per CDM: The treatment time on the Exposure CRF is 13:27 and the Vital Signs Post Dose Time of Assessment is 13:38 which has 11 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. 'Please clarify' the post dosing time of assessment and update as needed.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 19:04:08

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
User opened query 'Per CDM: The treatment time on the Exposure CRF is 13:27 and the Vital Signs Post Dose Time of Assessment is 13:38 which has 11 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. 'Please clarify' the post dosing time of assessment and update as needed.' (Site from DM). User entered '12:33'	(b) (4), (b) (6)	12 Oct 2020 11:57:14
	(b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered '9 Sep 2020 12:33'	System	23 Nov 2020 13:03:09
User entered '9 Sep 2020 11:35'	System	23 Nov 2020 13:01:41
User entered '9 Sep 2020 12:33'	System	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '64'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'bpm'	System	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '16'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'breaths/min'	System	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '122'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'mmHg'	System	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '82'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'mmHg'	System	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:57:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User closed query 'Per CDM re-query: Site response is noted. The Screening Date has been recently updated to 09Sep which is now the same date of the Visit 1 Day 1. Therefore, please remove the HEIGHT and WEIGHT and enter "ND-Not Done". Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 06:13:25
Query 'Per CDM re-query: Site response is noted. The Screening Date has been recently updated to 09Sep which is now the same date of the Visit 1 Day 1. Therefore, please remove the HEIGHT and WEIGHT and enter "ND-Not Done". Thank you.'	(b) (4), (b) (6)	02 Dec 2020 20:47:12
answered with 'UPDATED' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 20:47:07
User opened query 'Per CDM re-query: Site response is noted. The Screening Date has been recently updated to 09Sep which is now the same date of the Visit 1 Day 1. Therefore, please remove the HEIGHT and WEIGHT and enter "ND-Not Done". Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 14:34:12
User closed query ' Per CDM: Screening date is 01-sep-2020 and Visit day 1 is 09-sep-2020 which are not same. Hence Please update the missing data for Height and Weight for the 09-sep-2020 on this form. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 14:34:12
Query ' Per CDM: Screening date is 01-sep-2020 and Visit day 1 is 09-sep-2020 which are not same. Hence Please update the missing data for Height and Weight for the 09-sep-2020 on this form. Else Clarify. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 19:00:55
User entered '70' in reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:59:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:58:50

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:57:53

Height

Audit	User	Time (GMT)
User opened query ' Per CDM: Screening date is 01-sep-2020 and Visit day 1 is 09-sep-2020 which are not same. Hence Please update the missing data for Height and Weight for the 09-sep-2020 on this form. Else Clarify. ' (Site from DM). User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Oct 2020 12:25:58
	(b) (4), (b) (6) (b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:57:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 20:47:07
User entered '191.4' lb reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:59:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:58:50
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User closed query 'Per CDM: The treatment time on the Exposure CRF is 13:27 and the Vital Signs Post Dose Time of Assessment is 13:38 which has 11 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. 'Please clarify' the post dosing time of assessment and update as needed' (Site from DM). Query 'Per CDM: The treatment time on the Exposure CRF is 13:27 and the Vital Signs Post Dose Time of Assessment is 13:38 which has 11 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. 'Please clarify' the post dosing time of assessment and update as needed' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 07:14:45
Query 'Per CDM: The treatment time on the Exposure CRF is 13:27 and the Vital Signs Post Dose Time of Assessment is 13:38 which has 11 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. 'Please clarify' the post dosing time of assessment and update as needed' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 19:03:56
User entered '13:58' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 19:03:48
User opened query 'Per CDM: The treatment time on the Exposure CRF is 13:27 and the Vital Signs Post Dose Time of Assessment is 13:38 which has 11 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. 'Please clarify' the post dosing time of assessment and update as needed' (Site from DM). Query 'Per CDM: The treatment time on the Exposure CRF is 09:45 and the Vital Signs Post Dose Time of Assessment is 09:48 which has 11 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. 'Please clarify' the post dosing time of assessment and update as needed' canceled (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 08:55:10
Query 'Per CDM: The treatment time on the Exposure CRF is 09:45 and the Vital Signs Post Dose Time of Assessment is 09:48 which has 11 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. 'Please clarify' the post dosing time of assessment and update as needed' canceled (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 08:54:00

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
User opened query 'Per CDM: The treatment time on the Exposure CRF is 09:45 and the Vital Signs Post Dose Time of Assessment is 09:48 which has 11 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. 'Please clarify' the post dosing time of assessment and update as needed' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 08:53:56
Query 'Per CDM: The treatment time on the Exposure CRF is 13:27 and the Vital Signs Post Dose Time of Assessment is 13:38 which has 3 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. 'Please clarify' the post dosing time of assessment and update as needed' canceled (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 08:53:34
User opened query 'Per CDM: The treatment time on the Exposure CRF is 13:27 and the Vital Signs Post Dose Time of Assessment is 13:38 which has 3 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. 'Please clarify' the post dosing time of assessment and update as needed' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 08:53:27
User entered '13:38'	(b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered '9 Sep 2020 13:58'	System	16 Nov 2020 19:03:48
User entered '9 Sep 2020 13:38'	System	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '97.1' F	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '66'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'bpm'	System	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '16'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'breaths/min'	System	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '130'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'mmHg'	System	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '78'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'mmHg'	System	30 Sep 2020 15:37:11

US3822342

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:57:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:17

US3822342

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:57:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:17

US3822342

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	09 Sep 2020 17:40:07

US3822342

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	Kelly Woodell (b) (4)	09 Sep 2020 17:40:07

US3822342

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	Kelly Woodell (b) (4)	09 Sep 2020 17:40:07

US3822342

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 17:40:07

US3822342

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '09 Sep 2020'	Kelly Woodell (b) (4)	09 Sep 2020 17:40:07

US3822342

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '13:27'	Kelly Woodell (b) (4)	09 Sep 2020 17:40:07

US3822342

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered '09 Sep 2020 13:27'	System	09 Sep 2020 17:40:07

US3822342

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Right Arm (RIGHT ARM)'	Kelly Woodell (b) (4)	09 Sep 2020 17:40:07

US3822342

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'ONCE'	System	09 Sep 2020 17:40:07

US3822342

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 17:40:07

US3822342

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:36

US3822342

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:36

US3822342

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '12:46'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:36

US3822342

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered '9 Sep 2020 12:46'	System	30 Sep 2020 15:37:36

US3822342

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:57:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:47

US3822342

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:57:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	30 Sep 2020 15:37:47

US3822342

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:47

US3822342

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:57:53

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '13:20'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:47

US3822342

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:57:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered '9 Sep 2020 13:20'	System	30 Sep 2020 15:37:47

US3822342

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:57:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	30 Sep 2020 15:37:47

US3822342

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:47

US3822342

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:57:53

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:47

US3822342

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:57:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered empty.	System	30 Sep 2020 15:37:47

US3822342

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:37:51

US3822342

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered '1'	System	30 Sep 2020 15:37:51

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-09T13:59:34', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '7e77cc30-949c-4782-a060-36284a9ae7c2'	System	09 Sep 2020 18:00:07
User entered 'Yes (Y)'	System	09 Sep 2020 18:00:07

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-09T13:59:43', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '7e77cc30-949c-4782-a060-36284a9ae7c2' User entered '97.3'	System	09 Sep 2020 18:00:07
	System	09 Sep 2020 18:00:07

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-09T13:59:49', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '7e77cc30-949c-4782-a060-36284a9ae7c2'	System	09 Sep 2020 18:00:07
User entered 'No (N)'	System	09 Sep 2020 18:00:07

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-09T13:59:58', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '7e77cc30-949c-4782-a060-36284a9ae7c2'	System	09 Sep 2020 18:00:07
User entered '09 Sep 2020 13:59'	System	09 Sep 2020 18:00:07

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '09 Sep 2020 13:47'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '09 Sep 2020 16:17'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '09 Sep 2020 17:12'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered 'Day 2'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-10T16:01:47', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f84230e5-8c0e-44b7-8b8b-9b91b9fed996'	System	10 Sep 2020 20:06:59
User entered 'Yes (Y)'	System	10 Sep 2020 20:06:59

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-10T16:04:49', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f84230e5-8c0e-44b7-8b8b-9b91b9fed996' User entered '96.9'	System	10 Sep 2020 20:06:59
	System	10 Sep 2020 20:06:59

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-10T16:04:55', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f84230e5-8c0e-44b7-8b8b-9b91b9fed996'	System	10 Sep 2020 20:06:59
User entered 'No (N)'	System	10 Sep 2020 20:06:59

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-10T16:05:08', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f84230e5-8c0e-44b7-8b8b-9b91b9fed996'	System	10 Sep 2020 20:06:59
User entered '10 Sep 2020 16:05'	System	10 Sep 2020 20:06:59

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered 'Day 3'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-11T19:40:07', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '10d6f35f-b2e1-4171-88d0-21a4b5229ca7' User entered 'Yes (Y)'	System	11 Sep 2020 23:43:42
	System	11 Sep 2020 23:43:42

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-11T19:40:17', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '10d6f35f-b2e1-4171-88d0-21a4b5229ca7' User entered '98.2'	System	11 Sep 2020 23:43:42
	System	11 Sep 2020 23:43:42

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-11T19:40:21', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '10d6f35f-b2e1-4171-88d0-21a4b5229ca7'	System	11 Sep 2020 23:43:42
User entered 'No (N)'	System	11 Sep 2020 23:43:42

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-11T19:40:33', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '10d6f35f-b2e1-4171-88d0-21a4b5229ca7'	System	11 Sep 2020 23:43:42
User entered '11 Sep 2020 19:40'	System	11 Sep 2020 23:43:42

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered 'Day 4'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T00:30:10', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '33b89642-e9fe-49fd-ba28-4117f7022528' User entered 'Yes (Y)'	System	13 Sep 2020 04:30:53
	System	13 Sep 2020 04:30:53

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T00:30:34', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '33b89642-e9fe-49fd-ba28-4117f7022528' User entered '96.3'	System	13 Sep 2020 04:30:53
	System	13 Sep 2020 04:30:53

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T00:30:42', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '33b89642-e9fe-49fd-ba28-4117f7022528'	System	13 Sep 2020 04:30:53
User entered 'No (N)'	System	13 Sep 2020 04:30:53

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T00:30:49', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '33b89642-e9fe-49fd-ba28-4117f7022528' User entered '13 Sep 2020 00:30'	System	13 Sep 2020 04:30:53
	System	13 Sep 2020 04:30:53

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered 'Day 5'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T20:51:46', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '688a083f-26c9-42b0-91fa-dd21ead08ab3' User entered 'Yes (Y)'	System	14 Sep 2020 00:52:10
	System	14 Sep 2020 00:52:10

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T20:51:55', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '688a083f-26c9-42b0-91fa-dd21ead08ab3' User entered '97.4'	System	14 Sep 2020 00:52:10
	System	14 Sep 2020 00:52:10

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T20:51:59', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '688a083f-26c9-42b0-91fa-dd21ead08ab3'	System	14 Sep 2020 00:52:10
User entered 'No (N)'	System	14 Sep 2020 00:52:10

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T20:52:08', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '688a083f-26c9-42b0-91fa-dd21ead08ab3'	System	14 Sep 2020 00:52:10
User entered '13 Sep 2020 20:52'	System	14 Sep 2020 00:52:10

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered 'Day 6'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-14T17:41:20', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'e5cd8b7c-b3fa-4e62-bd73-5d7db36245b2'	System	14 Sep 2020 21:41:47
User entered 'Yes (Y)'	System	14 Sep 2020 21:41:47

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-14T17:41:26', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'e5cd8b7c-b3fa-4e62-bd73-5d7db36245b2' User entered '97.6'	System	14 Sep 2020 21:41:47
	System	14 Sep 2020 21:41:47

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-14T17:41:34', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'e5cd8b7c-b3fa-4e62-bd73-5d7db36245b2'	System	14 Sep 2020 21:41:47
User entered 'No (N)'	System	14 Sep 2020 21:41:47

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-14T17:41:45', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'e5cd8b7c-b3fa-4e62-bd73-5d7db36245b2'	System	14 Sep 2020 21:41:47
User entered '14 Sep 2020 17:41'	System	14 Sep 2020 21:41:47

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered 'Day 7'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-15T20:25:37', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '07913df9-143b-48eb-bf39-dc71d8f8a3e4' User entered 'Yes (Y)'	System	16 Sep 2020 00:26:10
	System	16 Sep 2020 00:26:10

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-15T20:25:44', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '07913df9-143b-48eb-bf39-dc71d8f8a3e4' User entered '97.1'	System	16 Sep 2020 00:26:10
	System	16 Sep 2020 00:26:10

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-15T20:25:50', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '07913df9-143b-48eb-bf39-dc71d8f8a3e4'	System	16 Sep 2020 00:26:10
User entered 'No (N)'	System	16 Sep 2020 00:26:10

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-15T20:26:07', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '07913df9-143b-48eb-bf39-dc71d8f8a3e4' User entered '15 Sep 2020 20:26'	System	16 Sep 2020 00:26:10
	System	16 Sep 2020 00:26:10

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-09T14:00:30', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '85a75c42-9f5e-4728-bacb-9ed1be619d21'	System	09 Sep 2020 18:00:49
User entered 'None (1)'	System	09 Sep 2020 18:00:49

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-09T14:00:34', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '85a75c42-9f5e-4728-bacb-9ed1be619d21'	System	09 Sep 2020 18:00:49
User entered 'No (N)'	System	09 Sep 2020 18:00:49

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-09T14:00:36', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '85a75c42-9f5e-4728-bacb-9ed1be619d21'	System	09 Sep 2020 18:00:49
User entered 'No (N)'	System	09 Sep 2020 18:00:49

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-09T14:00:41', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '85a75c42-9f5e-4728-bacb-9ed1be619d21'	System	09 Sep 2020 18:00:49
User entered 'None (1)'	System	09 Sep 2020 18:00:49

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-09T14:00:47', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '85a75c42-9f5e-4728-bacb-9ed1be619d21' User entered '09 Sep 2020 14:00'	System	09 Sep 2020 18:00:49
	System	09 Sep 2020 18:00:49

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '09 Sep 2020 13:47'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '09 Sep 2020 16:17'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '09 Sep 2020 17:12'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered 'Day 2'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-10T16:05:23', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'c50d1ac3-cf89-438f-82f7-e041de9a0bc0'	System	10 Sep 2020 20:07:00
User entered 'None (1)'	System	10 Sep 2020 20:07:00

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-10T16:05:28', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'c50d1ac3-cf89-438f-82f7-e041de9a0bc0' User entered 'No (N)'	System	10 Sep 2020 20:07:00
	System	10 Sep 2020 20:07:00

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-10T16:05:32', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'c50d1ac3-cf89-438f-82f7-e041de9a0bc0' User entered 'No (N)'	System	10 Sep 2020 20:07:00
	System	10 Sep 2020 20:07:00

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-10T16:05:57', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'c50d1ac3-cf89-438f-82f7-e041de9a0bc0' User entered 'None (1)'	System	10 Sep 2020 20:07:00
	System	10 Sep 2020 20:07:00

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-10T16:06:22', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'c50d1ac3-cf89-438f-82f7-e041de9a0bc0' User entered '10 Sep 2020 16:06'	System	10 Sep 2020 20:07:00
	System	10 Sep 2020 20:07:00

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered 'Day 3'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-11T19:40:48', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '24951485-1c7c-46c0-ac1d-985bce326fcd' User entered 'None (1)'	System	11 Sep 2020 23:43:45
	System	11 Sep 2020 23:43:45

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-11T19:40:46', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '24951485-1c7c-46c0-ac1d-985bce326fcd' User entered 'No (N)'	System	11 Sep 2020 23:43:45
	System	11 Sep 2020 23:43:45

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-11T19:40:53', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '24951485-1c7c-46c0-ac1d-985bce326fcd' User entered 'No (N)'	System	11 Sep 2020 23:43:45
	System	11 Sep 2020 23:43:45

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-11T19:40:58', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '24951485-1c7c-46c0-ac1d-985bce326fcd' User entered 'None (1)'	System	11 Sep 2020 23:43:45
	System	11 Sep 2020 23:43:45

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-11T19:41:07', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '24951485-1c7c-46c0-ac1d-985bce326fcd' User entered '11 Sep 2020 19:41'	System	11 Sep 2020 23:43:45
	System	11 Sep 2020 23:43:45

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered 'Day 4'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T00:30:55', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'cae6acf1-ef71-49e8-acf1-3fada5986b3a'	System	13 Sep 2020 04:31:14
User entered 'None (1)'	System	13 Sep 2020 04:31:14

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T00:30:58', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'cae6acf1-ef71-49e8-acf1-3fada5986b3a' User entered 'No (N)'	System	13 Sep 2020 04:31:14
	System	13 Sep 2020 04:31:14

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T00:31:01', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'cae6acf1-ef71-49e8-acf1-3fada5986b3a' User entered 'No (N)'	System	13 Sep 2020 04:31:14
	System	13 Sep 2020 04:31:14

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T00:31:05', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'cae6acf1-ef71-49e8-acf1-3fada5986b3a'	System	13 Sep 2020 04:31:14
User entered 'None (1)'	System	13 Sep 2020 04:31:14

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T00:31:12', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'cae6acf1-ef71-49e8-acf1-3fada5986b3a' User entered '13 Sep 2020 00:31'	System	13 Sep 2020 04:31:14
	System	13 Sep 2020 04:31:14

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered 'Day 5'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T20:52:15', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'd167a799-4ecb-4e6e-8d8f-922ee7b0b1f9'	System	14 Sep 2020 00:52:52
User entered 'None (1)'	System	14 Sep 2020 00:52:52

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T20:52:25', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'd167a799-4ecb-4e6e-8d8f-922ee7b0b1f9'	System	14 Sep 2020 00:52:52
User entered 'No (N)'	System	14 Sep 2020 00:52:52

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T20:52:39', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'd167a799-4ecb-4e6e-8d8f-922ee7b0b1f9'	System	14 Sep 2020 00:52:52
User entered 'No (N)'	System	14 Sep 2020 00:52:52

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T20:52:45', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'd167a799-4ecb-4e6e-8d8f-922ee7b0b1f9'	System	14 Sep 2020 00:52:52
User entered 'None (1)'	System	14 Sep 2020 00:52:52

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T20:52:51', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'd167a799-4ecb-4e6e-8d8f-922ee7b0b1f9'	System	14 Sep 2020 00:52:52
User entered '13 Sep 2020 20:52'	System	14 Sep 2020 00:52:52

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered 'Day 6'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-14T17:42:03', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f4318e0a-45b4-47a3-af23-c9903f303b0b'	System	14 Sep 2020 21:42:32
User entered 'None (1)'	System	14 Sep 2020 21:42:32

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-14T17:42:11', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f4318e0a-45b4-47a3-af23-c9903f303b0b' User entered 'No (N)'	System	14 Sep 2020 21:42:32
	System	14 Sep 2020 21:42:32

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-14T17:42:14', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f4318e0a-45b4-47a3-af23-c9903f303b0b' User entered 'No (N)'	System	14 Sep 2020 21:42:32
	System	14 Sep 2020 21:42:32

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-14T17:42:18', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f4318e0a-45b4-47a3-af23-c9903f303b0b'	System	14 Sep 2020 21:42:32
User entered 'None (1)'	System	14 Sep 2020 21:42:32

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-14T17:42:28', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f4318e0a-45b4-47a3-af23-c9903f303b0b' User entered '14 Sep 2020 17:42'	System	14 Sep 2020 21:42:32
	System	14 Sep 2020 21:42:32

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered 'Day 7'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-15T20:14:48', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '097ab389-f0c4-4b1a-8fa1-e76ac2d08b06'	System	16 Sep 2020 00:15:27
User entered 'None (1)'	System	16 Sep 2020 00:15:27

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-15T20:14:55', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '097ab389-f0c4-4b1a-8fa1-e76ac2d08b06' User entered 'No (N)'	System	16 Sep 2020 00:15:27
	System	16 Sep 2020 00:15:27

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-15T20:15:02', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '097ab389-f0c4-4b1a-8fa1-e76ac2d08b06' User entered 'No (N)'	System	16 Sep 2020 00:15:27
	System	16 Sep 2020 00:15:27

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-15T20:15:12', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '097ab389-f0c4-4b1a-8fa1-e76ac2d08b06'	System	16 Sep 2020 00:15:27
User entered 'None (1)'	System	16 Sep 2020 00:15:27

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-15T20:15:25', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '097ab389-f0c4-4b1a-8fa1-e76ac2d08b06' User entered '15 Sep 2020 20:15'	System	16 Sep 2020 00:15:27
	System	16 Sep 2020 00:15:27

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-09T14:01:01', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '6c0c99f3-3dae-4277-9d21-4db4d431e7c3' User entered 'None (0)'	System	09 Sep 2020 18:01:46
	System	09 Sep 2020 18:01:46

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-09T14:01:04', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '6c0c99f3-3dae-4277-9d21-4db4d431e7c3' User entered 'None (0)'	System	09 Sep 2020 18:01:46
	System	09 Sep 2020 18:01:46

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-09T14:01:09', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '6c0c99f3-3dae-4277-9d21-4db4d431e7c3' User entered 'None (0)'	System	09 Sep 2020 18:01:46
	System	09 Sep 2020 18:01:46

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-09T14:01:14', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '6c0c99f3-3dae-4277-9d21-4db4d431e7c3' User entered 'None (0)'	System	09 Sep 2020 18:01:46
	System	09 Sep 2020 18:01:46

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-09T14:01:19', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '6c0c99f3-3dae-4277-9d21-4db4d431e7c3' User entered 'None (0)'	System	09 Sep 2020 18:01:46
	System	09 Sep 2020 18:01:46

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-09T14:01:22', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '6c0c99f3-3dae-4277-9d21-4db4d431e7c3' User entered 'None (0)'	System	09 Sep 2020 18:01:46
	System	09 Sep 2020 18:01:46

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-09T14:01:34', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '6c0c99f3-3dae-4277-9d21-4db4d431e7c3'	System	09 Sep 2020 18:01:46
User entered 'No (N)'	System	09 Sep 2020 18:01:46

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-09T14:01:43', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '6c0c99f3-3dae-4277-9d21-4db4d431e7c3' User entered '09 Sep 2020 14:01'	System	09 Sep 2020 18:01:46
	System	09 Sep 2020 18:01:46

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '09 Sep 2020 13:47'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '09 Sep 2020 16:17'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '09 Sep 2020 17:12'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered 'Day 2'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-10T16:06:29', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'c4fbe748-a52f-490f-8b93-619f28991f22'	System	10 Sep 2020 20:08:42
User entered 'None (0)'	System	10 Sep 2020 20:08:42

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-10T16:06:42', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'c4fbe748-a52f-490f-8b93-619f28991f22'	System	10 Sep 2020 20:08:42
User entered 'None (0)'	System	10 Sep 2020 20:08:42

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-10T16:06:50', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'c4fbe748-a52f-490f-8b93-619f28991f22'	System	10 Sep 2020 20:08:42
User entered 'None (0)'	System	10 Sep 2020 20:08:42

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-10T16:07:04', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'c4fbe748-a52f-490f-8b93-619f28991f22'	System	10 Sep 2020 20:08:42
User entered 'None (0)'	System	10 Sep 2020 20:08:42

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-10T16:07:20', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'c4fbe748-a52f-490f-8b93-619f28991f22'	System	10 Sep 2020 20:08:42
User entered 'None (0)'	System	10 Sep 2020 20:08:42

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-10T16:07:26', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'c4fbe748-a52f-490f-8b93-619f28991f22'	System	10 Sep 2020 20:08:42
User entered 'None (0)'	System	10 Sep 2020 20:08:42

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-10T16:08:02', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'c4fbe748-a52f-490f-8b93-619f28991f22'	System	10 Sep 2020 20:08:42
User entered 'No (N)'	System	10 Sep 2020 20:08:42

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-10T16:08:13', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'c4fbe748-a52f-490f-8b93-619f28991f22'	System	10 Sep 2020 20:08:42
User entered '10 Sep 2020 16:08'	System	10 Sep 2020 20:08:42

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered 'Day 3'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-11T19:41:23', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'e9ad161b-9b0f-4fb4-b629-48f3fb986125' User entered 'None (0)'	System	11 Sep 2020 23:43:43
	System	11 Sep 2020 23:43:43

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-11T19:41:29', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'e9ad161b-9b0f-4fb4-b629-48f3fb986125' User entered 'None (0)'	System	11 Sep 2020 23:43:43
	System	11 Sep 2020 23:43:43

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-11T19:41:32', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'e9ad161b-9b0f-4fb4-b629-48f3fb986125' User entered 'None (0)'	System	11 Sep 2020 23:43:43
	System	11 Sep 2020 23:43:43

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-11T19:41:39', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'e9ad161b-9b0f-4fb4-b629-48f3fb986125' User entered 'None (0)'	System	11 Sep 2020 23:43:43
	System	11 Sep 2020 23:43:43

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-11T19:41:45', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'e9ad161b-9b0f-4fb4-b629-48f3fb986125' User entered 'None (0)'	System	11 Sep 2020 23:43:43
	System	11 Sep 2020 23:43:43

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-11T19:41:51', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'e9ad161b-9b0f-4fb4-b629-48f3fb986125' User entered 'None (0)'	System	11 Sep 2020 23:43:43
	System	11 Sep 2020 23:43:43

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-11T19:42:02', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'e9ad161b-9b0f-4fb4-b629-48f3fb986125'	System	11 Sep 2020 23:43:43
User entered 'No (N)'	System	11 Sep 2020 23:43:43

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-11T19:42:09', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'e9ad161b-9b0f-4fb4-b629-48f3fb986125'	System	11 Sep 2020 23:43:43
User entered '11 Sep 2020 19:42'	System	11 Sep 2020 23:43:43

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered 'Day 4'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T00:31:40', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '8a71d060-6b93-4f87-996b-b44736f5dbc7' User entered 'None (0)'	System	13 Sep 2020 04:32:09
	System	13 Sep 2020 04:32:09

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T00:31:43', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '8a71d060-6b93-4f87-996b-b44736f5dbc7' User entered 'None (0)'	System	13 Sep 2020 04:32:09
	System	13 Sep 2020 04:32:09

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T00:31:46', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '8a71d060-6b93-4f87-996b-b44736f5dbc7' User entered 'None (0)'	System	13 Sep 2020 04:32:09
	System	13 Sep 2020 04:32:09

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T00:31:49', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '8a71d060-6b93-4f87-996b-b44736f5dbc7' User entered 'None (0)'	System	13 Sep 2020 04:32:09
	System	13 Sep 2020 04:32:09

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T00:31:51', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '8a71d060-6b93-4f87-996b-b44736f5dbc7' User entered 'None (0)'	System	13 Sep 2020 04:32:09
	System	13 Sep 2020 04:32:09

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T00:31:54', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '8a71d060-6b93-4f87-996b-b44736f5dbc7' User entered 'None (0)'	System	13 Sep 2020 04:32:09
	System	13 Sep 2020 04:32:09

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T00:32:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '8a71d060-6b93-4f87-996b-b44736f5dbc7' User entered 'No (N)'	System	13 Sep 2020 04:32:09
	System	13 Sep 2020 04:32:09

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T00:32:06', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '8a71d060-6b93-4f87-996b-b44736f5dbc7' User entered '13 Sep 2020 00:32'	System	13 Sep 2020 04:32:09
	System	13 Sep 2020 04:32:09

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered 'Day 5'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T20:52:58', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'b3ecf3fc-0845-4c10-9e47-8edf32895e72'	System	14 Sep 2020 00:53:31
User entered 'None (0)'	System	14 Sep 2020 00:53:31

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T20:53:02', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'b3ecf3fc-0845-4c10-9e47-8edf32895e72'	System	14 Sep 2020 00:53:31
User entered 'None (0)'	System	14 Sep 2020 00:53:31

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T20:53:06', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'b3ecf3fc-0845-4c10-9e47-8edf32895e72'	System	14 Sep 2020 00:53:31
User entered 'None (0)'	System	14 Sep 2020 00:53:31

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T20:53:10', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'b3ecf3fc-0845-4c10-9e47-8edf32895e72' User entered 'None (0)'	System	14 Sep 2020 00:53:31
	System	14 Sep 2020 00:53:31

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T20:53:15', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'b3ecf3fc-0845-4c10-9e47-8edf32895e72' User entered 'None (0)'	System	14 Sep 2020 00:53:31
	System	14 Sep 2020 00:53:31

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T20:53:19', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'b3ecf3fc-0845-4c10-9e47-8edf32895e72'	System	14 Sep 2020 00:53:31
User entered 'None (0)'	System	14 Sep 2020 00:53:31

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T20:53:23', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'b3ecf3fc-0845-4c10-9e47-8edf32895e72'	System	14 Sep 2020 00:53:31
User entered 'No (N)'	System	14 Sep 2020 00:53:31

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-13T20:53:29', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'b3ecf3fc-0845-4c10-9e47-8edf32895e72'	System	14 Sep 2020 00:53:31
User entered '13 Sep 2020 20:53'	System	14 Sep 2020 00:53:31

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered 'Day 6'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-14T17:42:38', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '20908d27-843f-4534-a987-59d1bd6b6115' User entered 'None (0)'	System	14 Sep 2020 21:43:58
	System	14 Sep 2020 21:43:58

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-14T17:42:43', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '20908d27-843f-4534-a987-59d1bd6b6115' User entered 'None (0)'	System	14 Sep 2020 21:43:58
	System	14 Sep 2020 21:43:58

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-14T17:43:02', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '20908d27-843f-4534-a987-59d1bd6b6115' User entered 'None (0)'	System	14 Sep 2020 21:43:58
	System	14 Sep 2020 21:43:58

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-14T17:43:08', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '20908d27-843f-4534-a987-59d1bd6b6115' User entered 'None (0)'	System	14 Sep 2020 21:43:58
	System	14 Sep 2020 21:43:58

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-14T17:43:12', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '20908d27-843f-4534-a987-59d1bd6b6115' User entered 'None (0)'	System	14 Sep 2020 21:43:58
	System	14 Sep 2020 21:43:58

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-14T17:43:15', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '20908d27-843f-4534-a987-59d1bd6b6115' User entered 'None (0)'	System	14 Sep 2020 21:43:58
	System	14 Sep 2020 21:43:58

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-14T17:43:39', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '20908d27-843f-4534-a987-59d1bd6b6115'	System	14 Sep 2020 21:43:58
User entered 'No (N)'	System	14 Sep 2020 21:43:58

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-14T17:43:53', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '20908d27-843f-4534-a987-59d1bd6b6115' User entered '14 Sep 2020 17:43'	System	14 Sep 2020 21:43:58
	System	14 Sep 2020 21:43:58

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered 'Day 7'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-15T20:15:36', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'd92e7dec-424b-4fc0-ae17-39b1f266054c' User entered 'None (0)'	System	16 Sep 2020 00:16:49
	System	16 Sep 2020 00:16:49

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-15T20:15:41', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'd92e7dec-424b-4fc0-ae17-39b1f266054c' User entered 'None (0)'	System	16 Sep 2020 00:16:49
	System	16 Sep 2020 00:16:49

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-15T20:15:50', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'd92e7dec-424b-4fc0-ae17-39b1f266054c' User entered 'None (0)'	System	16 Sep 2020 00:16:49
	System	16 Sep 2020 00:16:49

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-15T20:15:56', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'd92e7dec-424b-4fc0-ae17-39b1f266054c' User entered 'None (0)'	System	16 Sep 2020 00:16:49
	System	16 Sep 2020 00:16:49

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-15T20:16:07', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'd92e7dec-424b-4fc0-ae17-39b1f266054c' User entered 'None (0)'	System	16 Sep 2020 00:16:49
	System	16 Sep 2020 00:16:49

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-15T20:16:26', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'd92e7dec-424b-4fc0-ae17-39b1f266054c' User entered 'None (0)'	System	16 Sep 2020 00:16:49
	System	16 Sep 2020 00:16:49

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-15T20:16:33', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'd92e7dec-424b-4fc0-ae17-39b1f266054c' User entered 'No (N)'	System	16 Sep 2020 00:16:49
	System	16 Sep 2020 00:16:49

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-09-15T20:16:46', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'd92e7dec-424b-4fc0-ae17-39b1f266054c' User entered '15 Sep 2020 20:16'	System	16 Sep 2020 00:16:49
	System	16 Sep 2020 00:16:49

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 17:40:07

US3822342

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 17:40:07

US3822342

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:38:16

US3822342

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:38:16

US3822342

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:38:16

US3822342

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:38:16

US3822342

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:38:20

US3822342

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'I'	System	30 Sep 2020 15:38:20

US3822342

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:04:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:38:33

US3822342

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:04:37
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:38:33

US3822342

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:04:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:38:33

US3822342

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:04:37
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:38:33

US3822342

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:04:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:38:36

US3822342

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'I'	System	30 Sep 2020 15:38:36

US3822342

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:04:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:26:11

US3822342

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:04:37
User entered '1 Oct 2020'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:26:11

US3822342

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:04:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:26:11

US3822342

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:04:37
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:26:11

US3822342

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:04:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:59:21

US3822342

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'I'	System	08 Oct 2020 14:59:21

US3822342

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User closed query 'Per GCL Lab Reconciliation: Requery 1: Immuno: Per response updated, however data on V3D57 is still missing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 09:57:16
Query 'Per GCL Lab Reconciliation: Requery 1: Immuno: Per response updated, however data on V3D57 is still missing.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 20:50:36
User opened query 'Per GCL Lab Reconciliation: Requery 1: Immuno: Per response updated, however data on V3D57 is still missing.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 10:33:15
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 02NOV2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 10:33:15
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 8OCT2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 08:41:40
Query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 02NOV2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 19:06:52
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 8OCT2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 19:06:47

US3822342

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 02NOV2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 00:08:57
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 8OCT2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 07:59:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 14:59:33

US3822342

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 08OCT2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 14:34:49
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 08OCT2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 19:06:57
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 08OCT2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 13:00:15
User entered '08 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 14:59:33

US3822342

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:59:33

US3822342

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'VISIT2'	System	08 Oct 2020 14:59:33

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '10:38'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered '8 Oct 2020 10:38'	System	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '68'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'bpm'	System	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '18'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'breaths/min'	System	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '134'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'mmHg'	System	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '84'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'mmHg'	System	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '11:20'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered '8 Oct 2020 11:20'	System	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '56'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'bpm'	System	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '16'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'breaths/min'	System	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '138'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'mmHg'	System	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '74'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'mmHg'	System	16 Nov 2020 19:05:42

US3822342

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:57:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:05:55

US3822342

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:57:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:05:55

US3822342

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:59:54

US3822342

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:59:54

US3822342

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:59:54

US3822342

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'MRNA-1273 OR PLACEBO'	System	08 Oct 2020 14:59:54

US3822342

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '08 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:59:54

US3822342

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '10:56'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:59:54

US3822342

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered '08 Oct 2020 10:56'	System	08 Oct 2020 14:59:54

US3822342

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:59:54

US3822342

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'ONCE'	System	08 Oct 2020 14:59:54

US3822342

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'INTRAMUSCULAR'	System	08 Oct 2020 14:59:54

US3822342

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 02NOV2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 09:57:19
Query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 02NOV2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 20:50:26
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 02NOV2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 19:47:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 19:06:13

US3822342

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:06:13

US3822342

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '10:46'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:06:13

US3822342

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered '8 Oct 2020 10:46'	System	16 Nov 2020 19:06:13

US3822342

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:57:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:06:24

US3822342

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:57:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	16 Nov 2020 19:06:24

US3822342

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:06:24

US3822342

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:57:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '10:50'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:06:24

US3822342

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:57:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered '8 Oct 2020 10:50'	System	16 Nov 2020 19:06:24

US3822342

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:57:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	16 Nov 2020 19:06:24

US3822342

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:06:24

US3822342

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:57:53

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:06:24

US3822342

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:57:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered empty.	System	16 Nov 2020 19:06:24

US3822342

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:00:00

US3822342

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'I'	System	08 Oct 2020 15:00:00

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	08 Oct 2020 14:59:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T11:22:31', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'cb5cb97a-b071-4574-adbd-93ed89c004f4' User entered 'Yes (Y)'	System	08 Oct 2020 15:22:56
	System	08 Oct 2020 15:22:56

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T11:22:40', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'cb5cb97a-b071-4574-adbd-93ed89c004f4' User entered '97.9'	System	08 Oct 2020 15:22:56
	System	08 Oct 2020 15:22:56

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T11:22:45', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'cb5cb97a-b071-4574-adbd-93ed89c004f4'	System	08 Oct 2020 15:22:56
User entered 'No (N)'	System	08 Oct 2020 15:22:56

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T11:22:52', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'cb5cb97a-b071-4574-adbd-93ed89c004f4' User entered '08 Oct 2020 11:22'	System	08 Oct 2020 15:22:56
	System	08 Oct 2020 15:22:56

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '08 Oct 2020 11:16'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '08 Oct 2020 13:46'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	08 Oct 2020 14:59:54
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T19:26:02', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '1a3b9926-629d-4eff-9634-e25629d71184' User entered 'Yes (Y)'	System	08 Oct 2020 23:26:37
	System	08 Oct 2020 23:26:37

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T19:26:13', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '1a3b9926-629d-4eff-9634-e25629d71184' User entered '98.5'	System	08 Oct 2020 23:26:37
	System	08 Oct 2020 23:26:37

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T19:26:20', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '1a3b9926-629d-4eff-9634-e25629d71184' User entered 'No (N)'	System	08 Oct 2020 23:26:37
	System	08 Oct 2020 23:26:37

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T19:26:34', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '1a3b9926-629d-4eff-9634-e25629d71184' User entered '08 Oct 2020 19:26'	System	08 Oct 2020 23:26:37
	System	08 Oct 2020 23:26:37

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '08 Oct 2020 14:41'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	08 Oct 2020 14:59:54
User entered 'Day 2'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-09T21:58:42', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'd1f829fb-7cc1-4f82-bc78-b50a14e3d134'	System	10 Oct 2020 02:00:55
User entered 'Yes (Y)'	System	10 Oct 2020 02:00:55

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-09T22:00:36', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'd1f829fb-7cc1-4f82-bc78-b50a14e3d134'	System	10 Oct 2020 02:00:55
User entered '96.8'	System	10 Oct 2020 02:00:55

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-09T22:00:41', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'd1f829fb-7cc1-4f82-bc78-b50a14e3d134'	System	10 Oct 2020 02:00:55
User entered 'No (N)'	System	10 Oct 2020 02:00:55

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-09T22:00:52', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'd1f829fb-7cc1-4f82-bc78-b50a14e3d134'	System	10 Oct 2020 02:00:55
User entered '09 Oct 2020 22:00'	System	10 Oct 2020 02:00:55

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	08 Oct 2020 14:59:54
User entered 'Day 3'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-10T21:30:07', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'bcc038d4-f72a-4f2d-bf5f-cec3cf0b23c8' User entered 'Yes (Y)'	System	11 Oct 2020 01:30:29
	System	11 Oct 2020 01:30:29

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-10T21:30:16', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'bcc038d4-f72a-4f2d-bf5f-cec3cf0b23c8' User entered '98.1'	System	11 Oct 2020 01:30:29
	System	11 Oct 2020 01:30:29

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-10T21:30:20', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'bcc038d4-f72a-4f2d-bf5f-cec3cf0b23c8'	System	11 Oct 2020 01:30:29
User entered 'No (N)'	System	11 Oct 2020 01:30:29

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-10T21:30:26', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'bcc038d4-f72a-4f2d-bf5f-cec3cf0b23c8' User entered '10 Oct 2020 21:30'	System	11 Oct 2020 01:30:29
	System	11 Oct 2020 01:30:29

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	08 Oct 2020 14:59:54
User entered 'Day 4'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-12T07:54:18', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '839f5bd3-cdec-4f8e-9c01-a075386cd4b2'	System	12 Oct 2020 11:58:20
User entered 'Yes (Y)'	System	12 Oct 2020 11:58:20

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-12T07:58:03', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '839f5bd3-cdec-4f8e-9c01-a075386cd4b2' User entered '97.7'	System	12 Oct 2020 11:58:20
	System	12 Oct 2020 11:58:20

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-12T07:58:07', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '839f5bd3-cdec-4f8e-9c01-a075386cd4b2'	System	12 Oct 2020 11:58:20
User entered 'No (N)'	System	12 Oct 2020 11:58:20

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-12T07:58:17', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '839f5bd3-cdec-4f8e-9c01-a075386cd4b2' User entered '12 Oct 2020 07:58'	System	12 Oct 2020 11:58:20
	System	12 Oct 2020 11:58:20

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	08 Oct 2020 14:59:54
User entered 'Day 5'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	08 Oct 2020 14:59:54
User entered 'Day 6'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-13T21:04:51', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '64b82b7f-dffb-4867-8b40-8fc318a50288' User entered 'Yes (Y)'	System	14 Oct 2020 01:06:29
	System	14 Oct 2020 01:06:29

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-13T21:06:18', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '64b82b7f-dffb-4867-8b40-8fc318a50288' User entered '98.2'	System	14 Oct 2020 01:06:29
	System	14 Oct 2020 01:06:29

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-13T21:06:22', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '64b82b7f-dffb-4867-8b40-8fc318a50288'	System	14 Oct 2020 01:06:29
User entered 'No (N)'	System	14 Oct 2020 01:06:29

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-13T21:06:26', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '64b82b7f-dffb-4867-8b40-8fc318a50288'	System	14 Oct 2020 01:06:29
User entered '13 Oct 2020 21:06'	System	14 Oct 2020 01:06:29

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	08 Oct 2020 14:59:54
User entered 'Day 7'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-14T13:22:28', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '73aa61f0-ab13-485f-8c0e-681bb003596d' User entered 'Yes (Y)'	System	14 Oct 2020 17:24:47
	System	14 Oct 2020 17:24:47

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-14T13:24:35', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '73aa61f0-ab13-485f-8c0e-681bb003596d' User entered '97.9'	System	14 Oct 2020 17:24:47
	System	14 Oct 2020 17:24:47

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-14T13:24:39', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '73aa61f0-ab13-485f-8c0e-681bb003596d' User entered 'No (N)'	System	14 Oct 2020 17:24:47
	System	14 Oct 2020 17:24:47

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-14T13:24:45', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '73aa61f0-ab13-485f-8c0e-681bb003596d' User entered '14 Oct 2020 13:24'	System	14 Oct 2020 17:24:47
	System	14 Oct 2020 17:24:47

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	08 Oct 2020 14:59:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T11:23:10', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'c59a3d79-d109-46c0-bf89-2fb6bcc59dbd'	System	08 Oct 2020 15:23:43
User entered 'None (1)'	System	08 Oct 2020 15:23:43

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T11:23:25', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'c59a3d79-d109-46c0-bf89-2fb6bcc59dbd' User entered 'No (N)'	System	08 Oct 2020 15:23:43
	System	08 Oct 2020 15:23:43

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T11:23:29', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'c59a3d79-d109-46c0-bf89-2fb6bcc59dbd' User entered 'No (N)'	System	08 Oct 2020 15:23:43
	System	08 Oct 2020 15:23:43

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T11:23:36', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'c59a3d79-d109-46c0-bf89-2fb6bcc59dbd'	System	08 Oct 2020 15:23:43
User entered 'None (1)'	System	08 Oct 2020 15:23:43

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T11:23:40', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'c59a3d79-d109-46c0-bf89-2fb6bcc59dbd' User entered '08 Oct 2020 11:23'	System	08 Oct 2020 15:23:43
	System	08 Oct 2020 15:23:43

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '08 Oct 2020 11:16'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '08 Oct 2020 13:46'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	08 Oct 2020 14:59:54
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T19:26:49', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f89a457d-61ad-426e-8059-748a361e787a' User entered 'None (1)'	System	08 Oct 2020 23:27:16
	System	08 Oct 2020 23:27:16

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T19:26:53', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f89a457d-61ad-426e-8059-748a361e787a' User entered 'No (N)'	System	08 Oct 2020 23:27:16
	System	08 Oct 2020 23:27:16

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T19:27:01', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f89a457d-61ad-426e-8059-748a361e787a' User entered 'No (N)'	System	08 Oct 2020 23:27:16
	System	08 Oct 2020 23:27:16

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T19:27:09', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f89a457d-61ad-426e-8059-748a361e787a' User entered 'None (1)'	System	08 Oct 2020 23:27:16
	System	08 Oct 2020 23:27:16

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T19:27:15', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f89a457d-61ad-426e-8059-748a361e787a' User entered '08 Oct 2020 19:27'	System	08 Oct 2020 23:27:16
	System	08 Oct 2020 23:27:16

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '08 Oct 2020 14:41'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	08 Oct 2020 14:59:54
User entered 'Day 2'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-09T22:01:06', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '11c2586e-3f4a-4340-bd95-14a34807f081'	System	10 Oct 2020 02:01:26
User entered 'None (1)'	System	10 Oct 2020 02:01:26

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-09T22:01:10', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '11c2586e-3f4a-4340-bd95-14a34807f081' User entered 'No (N)'	System	10 Oct 2020 02:01:26
	System	10 Oct 2020 02:01:26

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-09T22:01:13', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '11c2586e-3f4a-4340-bd95-14a34807f081' User entered 'No (N)'	System	10 Oct 2020 02:01:26
	System	10 Oct 2020 02:01:26

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-09T22:01:17', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '11c2586e-3f4a-4340-bd95-14a34807f081'	System	10 Oct 2020 02:01:26
User entered 'None (1)'	System	10 Oct 2020 02:01:26

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-09T22:01:23', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '11c2586e-3f4a-4340-bd95-14a34807f081' User entered '09 Oct 2020 22:01'	System	10 Oct 2020 02:01:26
	System	10 Oct 2020 02:01:26

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	08 Oct 2020 14:59:54
User entered 'Day 3'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-10T21:30:37', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '90db7640-091e-47b3-bd4d-946c1c48eee1'	System	11 Oct 2020 01:32:18
User entered 'None (1)'	System	11 Oct 2020 01:32:18

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-10T21:31:46', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '90db7640-091e-47b3-bd4d-946c1c48eee1' User entered 'No (N)'	System	11 Oct 2020 01:32:18
	System	11 Oct 2020 01:32:18

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-10T21:31:50', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '90db7640-091e-47b3-bd4d-946c1c48eee1' User entered 'No (N)'	System	11 Oct 2020 01:32:18
	System	11 Oct 2020 01:32:18

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-10T21:32:06', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '90db7640-091e-47b3-bd4d-946c1c48eee1' User entered 'None (1)'	System	11 Oct 2020 01:32:18
	System	11 Oct 2020 01:32:18

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-10T21:32:12', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '90db7640-091e-47b3-bd4d-946c1c48eee1' User entered '10 Oct 2020 21:32'	System	11 Oct 2020 01:32:18
	System	11 Oct 2020 01:32:18

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	08 Oct 2020 14:59:54
User entered 'Day 4'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-12T07:58:30', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '79e13abd-4674-4bd2-b90b-1e8c8aa97b54'	System	12 Oct 2020 11:58:55
User entered 'None (1)'	System	12 Oct 2020 11:58:55

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-12T07:58:34', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '79e13abd-4674-4bd2-b90b-1e8c8aa97b54' User entered 'No (N)'	System	12 Oct 2020 11:58:55
	System	12 Oct 2020 11:58:55

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-12T07:58:38', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '79e13abd-4674-4bd2-b90b-1e8c8aa97b54' User entered 'No (N)'	System	12 Oct 2020 11:58:55
	System	12 Oct 2020 11:58:55

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-12T07:58:46', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '79e13abd-4674-4bd2-b90b-1e8c8aa97b54' User entered 'None (1)'	System	12 Oct 2020 11:58:55
	System	12 Oct 2020 11:58:55

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-12T07:58:53', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '79e13abd-4674-4bd2-b90b-1e8c8aa97b54' User entered '12 Oct 2020 07:58'	System	12 Oct 2020 11:58:55
	System	12 Oct 2020 11:58:55

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	08 Oct 2020 14:59:54
User entered 'Day 5'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:53

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:53

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	08 Oct 2020 14:59:54
User entered 'Day 6'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-13T21:06:34', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'ae0c7149-946d-40c8-907f-a7e79cb1cf67'	System	14 Oct 2020 01:06:51
User entered 'None (1)'	System	14 Oct 2020 01:06:51

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-13T21:06:37', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'ae0c7149-946d-40c8-907f-a7e79cb1cf67'	System	14 Oct 2020 01:06:51
User entered 'No (N)'	System	14 Oct 2020 01:06:51

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-13T21:06:40', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'ae0c7149-946d-40c8-907f-a7e79cb1cf67'	System	14 Oct 2020 01:06:51
User entered 'No (N)'	System	14 Oct 2020 01:06:51

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-13T21:06:43', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'ae0c7149-946d-40c8-907f-a7e79cb1cf67'	System	14 Oct 2020 01:06:51
User entered 'None (1)'	System	14 Oct 2020 01:06:51

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-13T21:06:47', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'ae0c7149-946d-40c8-907f-a7e79cb1cf67'	System	14 Oct 2020 01:06:51
User entered '13 Oct 2020 21:06'	System	14 Oct 2020 01:06:51

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	08 Oct 2020 14:59:54
User entered 'Day 7'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-14T13:25:50', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '2a85edf3-c130-4a09-ac88-23f1043d9b17'	System	14 Oct 2020 17:26:17
User entered 'None (1)'	System	14 Oct 2020 17:26:17

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-14T13:25:55', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '2a85edf3-c130-4a09-ac88-23f1043d9b17'	System	14 Oct 2020 17:26:17
User entered 'No (N)'	System	14 Oct 2020 17:26:17

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-14T13:26:03', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '2a85edf3-c130-4a09-ac88-23f1043d9b17'	System	14 Oct 2020 17:26:17
User entered 'No (N)'	System	14 Oct 2020 17:26:17

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-14T13:26:09', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '2a85edf3-c130-4a09-ac88-23f1043d9b17'	System	14 Oct 2020 17:26:17
User entered 'None (1)'	System	14 Oct 2020 17:26:17

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-14T13:26:14', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '2a85edf3-c130-4a09-ac88-23f1043d9b17'	System	14 Oct 2020 17:26:17
User entered '14 Oct 2020 13:26'	System	14 Oct 2020 17:26:17

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	08 Oct 2020 14:59:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T11:23:49', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '9aac8493-da25-4b7e-b81c-4ec0af14bee0' User entered 'None (0)'	System	08 Oct 2020 15:24:21
	System	08 Oct 2020 15:24:21

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T11:23:52', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '9aac8493-da25-4b7e-b81c-4ec0af14bee0' User entered 'None (0)'	System	08 Oct 2020 15:24:21
	System	08 Oct 2020 15:24:21

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T11:23:56', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '9aac8493-da25-4b7e-b81c-4ec0af14bee0' User entered 'None (0)'	System	08 Oct 2020 15:24:21
	System	08 Oct 2020 15:24:21

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T11:24:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '9aac8493-da25-4b7e-b81c-4ec0af14bee0' User entered 'None (0)'	System	08 Oct 2020 15:24:21
	System	08 Oct 2020 15:24:21

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T11:24:03', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '9aac8493-da25-4b7e-b81c-4ec0af14bee0' User entered 'None (0)'	System	08 Oct 2020 15:24:21
	System	08 Oct 2020 15:24:21

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T11:24:06', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '9aac8493-da25-4b7e-b81c-4ec0af14bee0' User entered 'None (0)'	System	08 Oct 2020 15:24:21
	System	08 Oct 2020 15:24:21

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T11:24:13', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '9aac8493-da25-4b7e-b81c-4ec0af14bee0' User entered 'No (N)'	System	08 Oct 2020 15:24:21
	System	08 Oct 2020 15:24:21

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T11:24:17', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '9aac8493-da25-4b7e-b81c-4ec0af14bee0' User entered '08 Oct 2020 11:24'	System	08 Oct 2020 15:24:21
	System	08 Oct 2020 15:24:21

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '08 Oct 2020 11:16'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '08 Oct 2020 13:46'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	08 Oct 2020 14:59:54
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T19:27:27', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '721bf34b-f7dc-4832-8513-5d9a9b04c620' User entered 'None (0)'	System	08 Oct 2020 23:28:07
	System	08 Oct 2020 23:28:07

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T19:27:30', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '721bf34b-f7dc-4832-8513-5d9a9b04c620' User entered 'None (0)'	System	08 Oct 2020 23:28:07
	System	08 Oct 2020 23:28:07

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T19:27:34', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '721bf34b-f7dc-4832-8513-5d9a9b04c620' User entered 'None (0)'	System	08 Oct 2020 23:28:07
	System	08 Oct 2020 23:28:07

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T19:27:38', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '721bf34b-f7dc-4832-8513-5d9a9b04c620' User entered 'None (0)'	System	08 Oct 2020 23:28:07
	System	08 Oct 2020 23:28:07

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T19:27:42', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '721bf34b-f7dc-4832-8513-5d9a9b04c620' User entered 'None (0)'	System	08 Oct 2020 23:28:07
	System	08 Oct 2020 23:28:07

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T19:27:46', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '721bf34b-f7dc-4832-8513-5d9a9b04c620' User entered 'None (0)'	System	08 Oct 2020 23:28:07
	System	08 Oct 2020 23:28:07

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T19:27:52', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '721bf34b-f7dc-4832-8513-5d9a9b04c620'	System	08 Oct 2020 23:28:07
User entered 'No (N)'	System	08 Oct 2020 23:28:07

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-08T19:28:05', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '721bf34b-f7dc-4832-8513-5d9a9b04c620' User entered '08 Oct 2020 19:28'	System	08 Oct 2020 23:28:07
	System	08 Oct 2020 23:28:07

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '08 Oct 2020 14:41'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	08 Oct 2020 14:59:54
User entered 'Day 2'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-09T22:01:30', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '57ac3d8d-a693-4ebd-9fa9-ad003f593e5c' User entered 'None (0)'	System	10 Oct 2020 02:02:43
	System	10 Oct 2020 02:02:43

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-09T22:02:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '57ac3d8d-a693-4ebd-9fa9-ad003f593e5c' User entered 'None (0)'	System	10 Oct 2020 02:02:43
	System	10 Oct 2020 02:02:43

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-09T22:02:03', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '57ac3d8d-a693-4ebd-9fa9-ad003f593e5c' User entered 'None (0)'	System	10 Oct 2020 02:02:43
	System	10 Oct 2020 02:02:43

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-09T22:02:06', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '57ac3d8d-a693-4ebd-9fa9-ad003f593e5c' User entered 'None (0)'	System	10 Oct 2020 02:02:43
	System	10 Oct 2020 02:02:43

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-09T22:02:14', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '57ac3d8d-a693-4ebd-9fa9-ad003f593e5c' User entered 'None (0)'	System	10 Oct 2020 02:02:43
	System	10 Oct 2020 02:02:43

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-09T22:02:24', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '57ac3d8d-a693-4ebd-9fa9-ad003f593e5c' User entered 'None (0)'	System	10 Oct 2020 02:02:43
	System	10 Oct 2020 02:02:43

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-09T22:02:35', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '57ac3d8d-a693-4ebd-9fa9-ad003f593e5c' User entered 'No (N)'	System	10 Oct 2020 02:02:43
	System	10 Oct 2020 02:02:43

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-09T22:02:40', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '57ac3d8d-a693-4ebd-9fa9-ad003f593e5c' User entered '09 Oct 2020 22:02'	System	10 Oct 2020 02:02:43
	System	10 Oct 2020 02:02:43

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	08 Oct 2020 14:59:54
User entered 'Day 3'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-10T21:32:20', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f6c7fd19-5834-4c1c-8a08-f1d2017bdc25'	System	11 Oct 2020 01:32:58
User entered 'None (0)'	System	11 Oct 2020 01:32:58

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-10T21:32:24', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f6c7fd19-5834-4c1c-8a08-f1d2017bdc25'	System	11 Oct 2020 01:32:58
User entered 'None (0)'	System	11 Oct 2020 01:32:58

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-10T21:32:27', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f6c7fd19-5834-4c1c-8a08-f1d2017bdc25'	System	11 Oct 2020 01:32:58
User entered 'None (0)'	System	11 Oct 2020 01:32:58

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-10T21:32:31', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f6c7fd19-5834-4c1c-8a08-f1d2017bdc25'	System	11 Oct 2020 01:32:58
User entered 'None (0)'	System	11 Oct 2020 01:32:58

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-10T21:32:34', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f6c7fd19-5834-4c1c-8a08-f1d2017bdc25' User entered 'None (0)'	System	11 Oct 2020 01:32:58
	System	11 Oct 2020 01:32:58

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-10T21:32:38', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f6c7fd19-5834-4c1c-8a08-f1d2017bdc25'	System	11 Oct 2020 01:32:58
User entered 'None (0)'	System	11 Oct 2020 01:32:58

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-10T21:32:46', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f6c7fd19-5834-4c1c-8a08-f1d2017bdc25'	System	11 Oct 2020 01:32:58
User entered 'No (N)'	System	11 Oct 2020 01:32:58

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-10T21:32:55', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f6c7fd19-5834-4c1c-8a08-f1d2017bdc25'	System	11 Oct 2020 01:32:58
User entered '10 Oct 2020 21:32'	System	11 Oct 2020 01:32:58

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	08 Oct 2020 14:59:54
User entered 'Day 4'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-12T07:59:09', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '79bdf362-b70c-4c3e-8c9f-e91d286e1899'	System	12 Oct 2020 12:00:18
User entered 'None (0)'	System	12 Oct 2020 12:00:18

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-12T07:59:14', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '79bdf362-b70c-4c3e-8c9f-e91d286e1899' User entered 'None (0)'	System	12 Oct 2020 12:00:18
	System	12 Oct 2020 12:00:18

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-12T07:59:19', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '79bdf362-b70c-4c3e-8c9f-e91d286e1899' User entered 'None (0)'	System	12 Oct 2020 12:00:18
	System	12 Oct 2020 12:00:18

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-12T07:59:22', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '79bdf362-b70c-4c3e-8c9f-e91d286e1899' User entered 'None (0)'	System	12 Oct 2020 12:00:18
	System	12 Oct 2020 12:00:18

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-12T07:59:55', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '79bdf362-b70c-4c3e-8c9f-e91d286e1899'	System	12 Oct 2020 12:00:18
User entered 'None (0)'	System	12 Oct 2020 12:00:18

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-12T08:00:02', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '79bdf362-b70c-4c3e-8c9f-e91d286e1899'	System	12 Oct 2020 12:00:18
User entered 'None (0)'	System	12 Oct 2020 12:00:18

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-12T08:00:09', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '79bdf362-b70c-4c3e-8c9f-e91d286e1899'	System	12 Oct 2020 12:00:18
User entered 'No (N)'	System	12 Oct 2020 12:00:18

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-12T08:00:15', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '79bdf362-b70c-4c3e-8c9f-e91d286e1899'	System	12 Oct 2020 12:00:18
User entered '12 Oct 2020 08:00'	System	12 Oct 2020 12:00:18

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	08 Oct 2020 14:59:54
User entered 'Day 5'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	08 Oct 2020 14:59:54
User entered 'Day 6'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-13T21:06:52', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '928b7eb9-dc8e-4b6a-af50-bf41bea909ae' User entered 'None (0)'	System	14 Oct 2020 01:07:19
	System	14 Oct 2020 01:07:19

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-13T21:06:56', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '928b7eb9-dc8e-4b6a-af50-bf41bea909ae' User entered 'None (0)'	System	14 Oct 2020 01:07:19
	System	14 Oct 2020 01:07:19

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-13T21:07:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '928b7eb9-dc8e-4b6a-af50-bf41bea909ae' User entered 'None (0)'	System	14 Oct 2020 01:07:19
	System	14 Oct 2020 01:07:19

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-13T21:07:02', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '928b7eb9-dc8e-4b6a-af50-bf41bea909ae' User entered 'None (0)'	System	14 Oct 2020 01:07:19
	System	14 Oct 2020 01:07:19

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-13T21:07:04', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '928b7eb9-dc8e-4b6a-af50-bf41bea909ae' User entered 'None (0)'	System	14 Oct 2020 01:07:19
	System	14 Oct 2020 01:07:19

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-13T21:07:07', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '928b7eb9-dc8e-4b6a-af50-bf41bea909ae' User entered 'None (0)'	System	14 Oct 2020 01:07:19
	System	14 Oct 2020 01:07:19

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-13T21:07:13', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '928b7eb9-dc8e-4b6a-af50-bf41bea909ae' User entered 'No (N)'	System	14 Oct 2020 01:07:19
	System	14 Oct 2020 01:07:19

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-13T21:07:17', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '928b7eb9-dc8e-4b6a-af50-bf41bea909ae' User entered '13 Oct 2020 21:07'	System	14 Oct 2020 01:07:19
	System	14 Oct 2020 01:07:19

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	08 Oct 2020 14:59:54
User entered 'Day 7'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-14T13:26:20', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '10aeb68c-703c-4a3f-88cd-363ea4593d20' User entered 'None (0)'	System	14 Oct 2020 17:27:54
	System	14 Oct 2020 17:27:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-14T13:27:07', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '10aeb68c-703c-4a3f-88cd-363ea4593d20' User entered 'None (0)'	System	14 Oct 2020 17:27:54
	System	14 Oct 2020 17:27:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-14T13:27:10', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '10aeb68c-703c-4a3f-88cd-363ea4593d20' User entered 'None (0)'	System	14 Oct 2020 17:27:54
	System	14 Oct 2020 17:27:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-14T13:27:15', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '10aeb68c-703c-4a3f-88cd-363ea4593d20' User entered 'None (0)'	System	14 Oct 2020 17:27:54
	System	14 Oct 2020 17:27:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-14T13:27:30', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '10aeb68c-703c-4a3f-88cd-363ea4593d20' User entered 'None (0)'	System	14 Oct 2020 17:27:54
	System	14 Oct 2020 17:27:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-14T13:27:36', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '10aeb68c-703c-4a3f-88cd-363ea4593d20' User entered 'None (0)'	System	14 Oct 2020 17:27:54
	System	14 Oct 2020 17:27:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-14T13:27:43', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '10aeb68c-703c-4a3f-88cd-363ea4593d20' User entered 'No (N)'	System	14 Oct 2020 17:27:54
	System	14 Oct 2020 17:27:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-10-14T13:27:50', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '10aeb68c-703c-4a3f-88cd-363ea4593d20' User entered '14 Oct 2020 13:27'	System	14 Oct 2020 17:27:54
	System	14 Oct 2020 17:27:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 14:59:54

US3822342

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:57:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 14:59:54

US3822342

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:04:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:48:19

US3822342

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:04:37
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:48:19

US3822342

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:04:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:48:19

US3822342

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:04:37
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:48:19

US3822342

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:04:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:48:22

US3822342

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'I'	System	02 Dec 2020 20:48:22

US3822342

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:04:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:48:32

US3822342

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:04:37
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:48:32

US3822342

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:04:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:48:32

US3822342

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:04:37
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:48:32

US3822342

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:04:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:48:35

US3822342

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'I'	System	02 Dec 2020 20:48:35

US3822342

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:04:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:48:47

US3822342

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:04:37
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:48:47

US3822342

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:04:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:48:47

US3822342

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:04:37
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:48:47

US3822342

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:04:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:48:49

US3822342

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'I'	System	02 Dec 2020 20:48:49

US3822342

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:37
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:49:00

US3822342

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:37
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '2 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:49:00

US3822342

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:37
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:49:00

US3822342

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:37
User entered 'VISIT3'	System	02 Dec 2020 20:49:00

US3822342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:37
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:49:22

US3822342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:37
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '2 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:49:22

US3822342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:37
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '10:15'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:49:22

US3822342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:37
User entered '2 Nov 2020 10:15'	System	02 Dec 2020 20:49:22

US3822342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:37
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '97.4' F	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:49:22

US3822342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:37
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:49:22

US3822342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:37
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:49:22

US3822342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:37
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '63'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:49:22

US3822342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:37
User entered 'bpm'	System	02 Dec 2020 20:49:22

US3822342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:37
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '15'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:49:22

US3822342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:37
User entered 'breaths/min'	System	02 Dec 2020 20:49:22

US3822342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:37
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '137'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:49:22

US3822342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:37
User entered 'mmHg'	System	02 Dec 2020 20:49:22

US3822342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:37
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '80'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:49:22

US3822342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:37
User entered 'mmHg'	System	02 Dec 2020 20:49:22

US3822342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:37

US3822342

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:37

US3822342

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:57:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:49:30

US3822342

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:57:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:49:30

US3822342

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:49:39

US3822342

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '2 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:49:39

US3822342

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered '10:18'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:49:39

US3822342

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered '2 Nov 2020 10:18'	System	02 Dec 2020 20:49:39

US3822342

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:05:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:49:42

US3822342

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'I'	System	02 Dec 2020 20:49:42

US3822342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered 'Day 64'	System	09 Sep 2020 17:40:07

US3822342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-11-10T23:06:38', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'a60e961b-0d2d-46a0-bc12-0e171c418fdf'	System	11 Nov 2020 04:07:12
User entered 'No (N)'	System	11 Nov 2020 04:07:12

US3822342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Have you been exposed to someone with 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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-11-10T23:06:47', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'a60e961b-0d2d-46a0-bc12-0e171c418fdf'	System	11 Nov 2020 04:07:12
User entered 'No (N)'	System	11 Nov 2020 04:07:12

US3822342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-11-10T23:07:09', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'a60e961b-0d2d-46a0-bc12-0e171c418fdf' User entered '10 Nov 2020 23:07:09'	System	11 Nov 2020 04:07:12
	System	11 Nov 2020 04:07:12

US3822342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered '09 Nov 2020 00:01'	System	09 Sep 2020 17:40:07

US3822342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered '13 Nov 2020 23:59'	System	09 Sep 2020 17:40:07

US3822342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered 'Day 71'	System	09 Sep 2020 17:40:07

US3822342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-11-18T15:28:07', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'abf91c01-7575-489c-850e-62665672d6a2'	System	18 Nov 2020 20:28:29
User entered 'No (N)'	System	18 Nov 2020 20:28:29

US3822342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Have you been exposed to someone with 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 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-11-18T15:28:13', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'abf91c01-7575-489c-850e-62665672d6a2'	System	18 Nov 2020 20:28:29
User entered 'No (N)'	System	18 Nov 2020 20:28:29

US3822342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-11-18T15:28:24', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'abf91c01-7575-489c-850e-62665672d6a2'	System	18 Nov 2020 20:28:29
User entered '18 Nov 2020 15:28:24'	System	18 Nov 2020 20:28:29

US3822342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered '16 Nov 2020 00:01'	System	09 Sep 2020 17:40:07

US3822342

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:06:09
Data entry locked.	System	09 Sep 2020 17:40:07
User entered '20 Nov 2020 23:59'	System	09 Sep 2020 17:40:07

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-11-20T00:20:32', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'aabca9e7-fa93-4bc6-8fa7-4f58efda0018'	System	20 Nov 2020 05:21:07
User entered 'No (N)'	System	20 Nov 2020 05:21:07

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Have you been exposed to someone with 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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-11-20T00:20:51', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'aabca9e7-fa93-4bc6-8fa7-4f58efda0018' User entered 'No (N)'	System	20 Nov 2020 05:21:07

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-11-20T00:21:05', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'aabca9e7-fa93-4bc6-8fa7-4f58efda0018' User entered '20 Nov 2020 00:21:05'	System	20 Nov 2020 05:21:07
	System	20 Nov 2020 05:21:07

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-11-27T07:34:49', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '9265993c-7a3f-402b-960d-694305f26f3c' User entered 'No (N)'	System	27 Nov 2020 12:35:30
	System	27 Nov 2020 12:35:30

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Have you been exposed to someone with 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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-11-27T07:35:07', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '9265993c-7a3f-402b-960d-694305f26f3c' User entered 'No (N)'	System	27 Nov 2020 12:35:30

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-11-27T07:35:28', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '9265993c-7a3f-402b-960d-694305f26f3c' User entered '27 Nov 2020 07:35:28'	System	27 Nov 2020 12:35:30
	System	27 Nov 2020 12:35:30

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-12-04T07:24:32', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '8ab559d2-6819-46c0-bab6-d57929407c4a'	System	04 Dec 2020 12:25:46
User entered 'No (N)'	System	04 Dec 2020 12:25:46

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Have you been exposed to someone with 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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-12-04T07:25:03', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '8ab559d2-6819-46c0-bab6-d57929407c4a'	System	04 Dec 2020 12:25:46
User entered 'No (N)'	System	04 Dec 2020 12:25:46

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-12-04T07:25:43', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '8ab559d2-6819-46c0-bab6-d57929407c4a' User entered '04 Dec 2020 07:25:43'	System	04 Dec 2020 12:25:46
	System	04 Dec 2020 12:25:46

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-12-13T08:07:43', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'fe02b4f3-0d63-4ff3-a3ab-7c900a17856e'	System	13 Dec 2020 13:08:36
User entered 'No (N)'	System	13 Dec 2020 13:08:36

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Have you been exposed to someone with 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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-12-13T08:08:16', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'fe02b4f3-0d63-4ff3-a3ab-7c900a17856e'	System	13 Dec 2020 13:08:36
User entered 'No (N)'	System	13 Dec 2020 13:08:36

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-12-13T08:08:34', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'fe02b4f3-0d63-4ff3-a3ab-7c900a17856e' User entered '13 Dec 2020 08:08:34'	System	13 Dec 2020 13:08:36
	System	13 Dec 2020 13:08:36

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-12-18T00:01:48', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '201b922b-5c68-42e3-8f93-1c72c4c30022'	System	18 Dec 2020 05:02:28
User entered 'No (N)'	System	18 Dec 2020 05:02:28

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Have you been exposed to someone with 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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-12-18T00:01:55', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '201b922b-5c68-42e3-8f93-1c72c4c30022'	System	18 Dec 2020 05:02:28
User entered 'No (N)'	System	18 Dec 2020 05:02:28

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-12-18T00:02:12', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '201b922b-5c68-42e3-8f93-1c72c4c30022' User entered '18 Dec 2020 00:02:12'	System	18 Dec 2020 05:02:28
	System	18 Dec 2020 05:02:28

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-12-25T18:59:17', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '9b8868f2-5378-4aa0-8502-d0030517de31'	System	26 Dec 2020 00:00:22
User entered 'Yes (Y)'	System	26 Dec 2020 00:00:22

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Have you been exposed to someone with 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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-12-25T18:59:26', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '9b8868f2-5378-4aa0-8502-d0030517de31'	System	26 Dec 2020 00:00:22
User entered 'No (N)'	System	26 Dec 2020 00:00:22

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-12-25T18:59:32', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '9b8868f2-5378-4aa0-8502-d0030517de31'	System	26 Dec 2020 00:00:22
User entered 'No (N)'	System	26 Dec 2020 00:00:22

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-12-25T18:59:41', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '9b8868f2-5378-4aa0-8502-d0030517de31'	System	26 Dec 2020 00:00:22
User entered 'No (N)'	System	26 Dec 2020 00:00:22

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2020-12-25T19:00:15', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '9b8868f2-5378-4aa0-8502-d0030517de31'	System	26 Dec 2020 00:00:22
User entered '25 Dec 2020 19:00:15'	System	26 Dec 2020 00:00:22

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-01-01T14:27:37', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f4749c36-c585-475b-ae20-e1e4d3500767'	System	01 Jan 2021 19:28:05
User entered 'No (N)'	System	01 Jan 2021 19:28:05

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Have you been exposed to someone with 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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-01-01T14:27:49', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f4749c36-c585-475b-ae20-e1e4d3500767'	System	01 Jan 2021 19:28:05
User entered 'No (N)'	System	01 Jan 2021 19:28:05

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-01-01T14:28:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f4749c36-c585-475b-ae20-e1e4d3500767' User entered '01 Jan 2021 14:28:00'	System	01 Jan 2021 19:28:05
	System	01 Jan 2021 19:28:05

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-01-09T01:03:08', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '6e92266b-b960-4db8-9c00-72f277e2b0b1' User entered 'No (N)'	System	09 Jan 2021 06:03:45
	System	09 Jan 2021 06:03:45

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Have you been exposed to someone with 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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-01-09T01:03:20', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '6e92266b-b960-4db8-9c00-72f277e2b0b1'	System	09 Jan 2021 06:03:45
User entered 'No (N)'	System	09 Jan 2021 06:03:45

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-01-09T01:03:38', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '6e92266b-b960-4db8-9c00-72f277e2b0b1' User entered '09 Jan 2021 01:03:38'	System	09 Jan 2021 06:03:45
	System	09 Jan 2021 06:03:45

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-01-15T23:53:23', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '0c09640e-13f0-4a2b-9466-5579944de9b1'	System	16 Jan 2021 04:53:53
User entered 'No (N)'	System	16 Jan 2021 04:53:53

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Have you been exposed to someone with 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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-01-15T23:53:31', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '0c09640e-13f0-4a2b-9466-5579944de9b1' User entered 'No (N)'	System	16 Jan 2021 04:53:53
	System	16 Jan 2021 04:53:53

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-01-15T23:53:50', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '0c09640e-13f0-4a2b-9466-5579944de9b1' User entered '15 Jan 2021 23:53:50'	System	16 Jan 2021 04:53:53

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-01-22T00:01:36', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'a5fec685-bc49-4c32-8ae3-bddee1f9f979'	System	22 Jan 2021 05:02:11
User entered 'No (N)'	System	22 Jan 2021 05:02:11

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Have you been exposed to someone with 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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-01-22T00:01:43', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'a5fec685-bc49-4c32-8ae3-bddee1f9f979'	System	22 Jan 2021 05:02:11
User entered 'No (N)'	System	22 Jan 2021 05:02:11

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-01-22T00:01:55', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'a5fec685-bc49-4c32-8ae3-bddee1f9f979'	System	22 Jan 2021 05:02:11
User entered '22 Jan 2021 00:01:55'	System	22 Jan 2021 05:02:11

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-01-30T07:54:01', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '6c8d996f-b644-4931-a4a3-f44e17eb1599'	System	30 Jan 2021 12:54:18
User entered 'No (N)'	System	30 Jan 2021 12:54:18

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Have you been exposed to someone with 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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-01-30T07:54:07', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '6c8d996f-b644-4931-a4a3-f44e17eb1599'	System	30 Jan 2021 12:54:18
User entered 'No (N)'	System	30 Jan 2021 12:54:18

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-01-30T07:54:14', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '6c8d996f-b644-4931-a4a3-f44e17eb1599' User entered '30 Jan 2021 07:54:14'	System	30 Jan 2021 12:54:18
	System	30 Jan 2021 12:54:18

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-02-08T23:59:29', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '31d6f08a-02ad-4573-b405-b44b7a9ffc13'	System	09 Feb 2021 05:00:32
User entered 'Yes (Y)'	System	09 Feb 2021 05:00:32

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Have you been exposed to someone with 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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-02-08T23:59:36', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '31d6f08a-02ad-4573-b405-b44b7a9ffc13'	System	09 Feb 2021 05:00:32
User entered 'No (N)'	System	09 Feb 2021 05:00:32

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-02-08T23:59:42', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '31d6f08a-02ad-4573-b405-b44b7a9ffc13'	System	09 Feb 2021 05:00:32
User entered 'No (N)'	System	09 Feb 2021 05:00:32

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-02-08T23:59:50', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '31d6f08a-02ad-4573-b405-b44b7a9ffc13'	System	09 Feb 2021 05:00:32
User entered 'Yes (Y)'	System	09 Feb 2021 05:00:32

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Please 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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-02-09T00:00:02', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '31d6f08a-02ad-4573-b405-b44b7a9ffc13'	System	09 Feb 2021 05:00:32
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Feb 2021 05:00:32

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-02-09T00:00:19', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '31d6f08a-02ad-4573-b405-b44b7a9ffc13' User entered '09 Feb 2021 00:00:19'	System	09 Feb 2021 05:00:32
	System	09 Feb 2021 05:00:32

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-02-12T23:33:59', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f16a8a44-a2ac-4c0a-9465-603eacda8041' User entered 'No (N)'	System	13 Feb 2021 04:34:12

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Have you been exposed to someone with 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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-02-12T23:33:10', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f16a8a44-a2ac-4c0a-9465-603eacda8041'	System	13 Feb 2021 04:34:12
User entered 'No (N)'	System	13 Feb 2021 04:34:12

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-02-12T23:34:09', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'f16a8a44-a2ac-4c0a-9465-603eacda8041' User entered '12 Feb 2021 23:34:09'	System	13 Feb 2021 04:34:12
	System	13 Feb 2021 04:34:12

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-02-19T00:39:13', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'a4474d73-7f41-43c4-b031-16a8c7c75a0a' User entered 'No (N)'	System	19 Feb 2021 05:39:38
	System	19 Feb 2021 05:39:38

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Have you been exposed to someone with 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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-02-19T00:39:21', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'a4474d73-7f41-43c4-b031-16a8c7c75a0a' User entered 'No (N)'	System	19 Feb 2021 05:39:38
	System	19 Feb 2021 05:39:38

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-02-19T00:39:35', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'a4474d73-7f41-43c4-b031-16a8c7c75a0a' User entered '19 Feb 2021 00:39:35'	System	19 Feb 2021 05:39:38
	System	19 Feb 2021 05:39:38

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-02-26T07:56:36-05:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '766acc07-e314-4795-b367-f7c4b9dffdcc'	System	26 Feb 2021 12:57:19
User entered 'No (N)'	System	26 Feb 2021 12:57:19

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Have you been exposed to someone with 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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-02-26T07:56:47-05:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '766acc07-e314-4795-b367-f7c4b9dffdcc'	System	26 Feb 2021 12:57:19
User entered 'No (N)'	System	26 Feb 2021 12:57:19

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-02-26T07:57:17-05:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '766acc07-e314-4795-b367-f7c4b9dffdcc' User entered '26 Feb 2021 12:57:17'	System	26 Feb 2021 12:57:19
	System	26 Feb 2021 12:57:19

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-03-05T00:47:52-05:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'ff2aea0d-7173-445d-8597-d50de068bb53'	System	05 Mar 2021 05:48:19
User entered 'No (N)'	System	05 Mar 2021 05:48:19

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Have you been exposed to someone with 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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-03-05T00:48:01-05:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'ff2aea0d-7173-445d-8597-d50de068bb53'	System	05 Mar 2021 05:48:19
User entered 'No (N)'	System	05 Mar 2021 05:48:19

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-03-05T00:48:17-05:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'ff2aea0d-7173-445d-8597-d50de068bb53' User entered '05 Mar 2021 00:48:17'	System	05 Mar 2021 05:48:19
	System	05 Mar 2021 05:48:19

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-03-13T07:21:03-05:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '38f59005-55a7-4a94-8cbf-64fc4e83e63b'	System	13 Mar 2021 12:21:22
User entered 'No (N)'	System	13 Mar 2021 12:21:22

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Have you been exposed to someone with 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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-03-13T07:21:10-05:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '38f59005-55a7-4a94-8cbf-64fc4e83e63b'	System	13 Mar 2021 12:21:22
User entered 'No (N)'	System	13 Mar 2021 12:21:22

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-03-13T07:21:17-05:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '38f59005-55a7-4a94-8cbf-64fc4e83e63b'	System	13 Mar 2021 12:21:22
User entered '13 Mar 2021 07:21:17'	System	13 Mar 2021 12:21:22

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-03-20T01:40:56-04:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '7a25b0ae-fe65-403c-9426-8ac17dd62ffc'	System	20 Mar 2021 05:41:19
User entered 'No (N)'	System	20 Mar 2021 05:41:19

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Have you been exposed to someone with 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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-03-20T01:41:03-04:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '7a25b0ae-fe65-403c-9426-8ac17dd62ffc'	System	20 Mar 2021 05:41:19
User entered 'No (N)'	System	20 Mar 2021 05:41:19

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-03-20T01:41:15-04:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '7a25b0ae-fe65-403c-9426-8ac17dd62ffc' User entered '20 Mar 2021 01:41:15'	System	20 Mar 2021 05:41:19
	System	20 Mar 2021 05:41:19

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-03-26T00:29:36-04:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '175b8a25-9582-4980-9600-7a2507b961d1'	System	26 Mar 2021 04:29:53
User entered 'No (N)'	System	26 Mar 2021 04:29:53

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Have you been exposed to someone with 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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-03-26T00:29:43-04:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '175b8a25-9582-4980-9600-7a2507b961d1'	System	26 Mar 2021 04:29:53
User entered 'No (N)'	System	26 Mar 2021 04:29:53

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-03-26T00:29:50-04:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '175b8a25-9582-4980-9600-7a2507b961d1'	System	26 Mar 2021 04:29:53
User entered '26 Mar 2021 00:29:50'	System	26 Mar 2021 04:29:53

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-04-03T06:43:48-04:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '9608df12-b177-4b88-b95a-93c72347e07e'	System	03 Apr 2021 10:44:20
User entered 'No (N)'	System	03 Apr 2021 10:44:20

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Have you been exposed to someone with 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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-04-03T06:44:13-04:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '9608df12-b177-4b88-b95a-93c72347e07e'	System	03 Apr 2021 10:44:20
User entered 'No (N)'	System	03 Apr 2021 10:44:20

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-04-03T06:44:18-04:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '9608df12-b177-4b88-b95a-93c72347e07e'	System	03 Apr 2021 10:44:20
User entered '03 Apr 2021 06:44:18'	System	03 Apr 2021 10:44:20

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-04-09T09:42:00-04:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'be93e521-7bac-41e4-83b7-3e5adac5d115'	System	09 Apr 2021 13:42:16
User entered 'No (N)'	System	09 Apr 2021 13:42:16

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Have you been exposed to someone with 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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-04-09T09:42:05-04:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'be93e521-7bac-41e4-83b7-3e5adac5d115'	System	09 Apr 2021 13:42:16
User entered 'No (N)'	System	09 Apr 2021 13:42:16

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-04-09T09:42:10-04:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'be93e521-7bac-41e4-83b7-3e5adac5d115'	System	09 Apr 2021 13:42:16
User entered '09 Apr 2021 09:42:10'	System	09 Apr 2021 13:42:16

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-04-17T10:51:04-04:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '53b5777c-0fb5-40ce-8b0e-ab4d9d909ae2'	System	17 Apr 2021 14:51:27
User entered 'No (N)'	System	17 Apr 2021 14:51:27

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Have you been exposed to someone with 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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-04-17T10:51:13-04:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '53b5777c-0fb5-40ce-8b0e-ab4d9d909ae2'	System	17 Apr 2021 14:51:27
User entered 'No (N)'	System	17 Apr 2021 14:51:27

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-04-17T10:51:23-04:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '53b5777c-0fb5-40ce-8b0e-ab4d9d909ae2' User entered '17 Apr 2021 10:51:23'	System	17 Apr 2021 14:51:27
	System	17 Apr 2021 14:51:27

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-04-23T11:04:13-04:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '170d4a0e-73d3-42bc-b188-9fd71e28fc1c'	System	23 Apr 2021 15:04:37
User entered 'No (N)'	System	23 Apr 2021 15:04:37

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Have you been exposed to someone with 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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-04-23T11:04:27-04:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '170d4a0e-73d3-42bc-b188-9fd71e28fc1c'	System	23 Apr 2021 15:04:37
User entered 'No (N)'	System	23 Apr 2021 15:04:37

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-04-23T11:04:31-04:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '170d4a0e-73d3-42bc-b188-9fd71e28fc1c'	System	23 Apr 2021 15:04:37
User entered '23 Apr 2021 11:04:31'	System	23 Apr 2021 15:04:37

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-04-30T08:31:25-04:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'ddffa4a4-44da-4057-9f03-60446ba7cb9c'	System	30 Apr 2021 12:31:40
User entered 'No (N)'	System	30 Apr 2021 12:31:40

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

Have you been exposed to someone with 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 (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-04-30T08:31:30-04:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'ddffa4a4-44da-4057-9f03-60446ba7cb9c'	System	30 Apr 2021 12:31:40
User entered 'No (N)'	System	30 Apr 2021 12:31:40

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-04-30T08:31:36-04:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: 'ddffa4a4-44da-4057-9f03-60446ba7cb9c'	System	30 Apr 2021 12:31:40
User entered '30 Apr 2021 08:31:36'	System	30 Apr 2021 12:31:40

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '28 Oct 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '01 Nov 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '04 Nov 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '08 Nov 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '11 Nov 2022 00:01'	System	19 Nov 2020 21:51:50

US3822342

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:57:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '15 Nov 2022 23:59'	System	19 Nov 2020 21:51:50

US3822342

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:57:53

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 18:53:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-02-27T17:59:26-05:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '71a7faad-9a70-4643-ab87-ca50eee73333'	System	27 Feb 2021 22:59:42
User entered 'No (N)'	System	27 Feb 2021 22:59:42

US3822342

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:57:53

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:53:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC82DF2D-0E7B-44DF-AD02-E9268C7147C1)', Time: '2021-02-27T17:59:40-05:00', User OID: 'PatientReportedOutcome (US3822342)', ODM File OID: '71a7faad-9a70-4643-ab87-ca50eee73333'	System	27 Feb 2021 22:59:42
User entered '27 Feb 2021 22:59:40'	System	27 Feb 2021 22:59:42

US3822342

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:24:40
User entered 'Yes (Y)'	Krishna Shah (b) (4)	10 Dec 2020 16:17:53

US3822342

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:24:40
User entered '1 Dec 2020'	Krishna Shah (b) (4)	10 Dec 2020 16:17:53

US3822342

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:24:40
User entered 'Contact Made (CONTACT MADE)'	Krishna Shah (b) (4)	10 Dec 2020 16:17:53

US3822342

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:24:40
User entered empty.	Krishna Shah (b) (4)	10 Dec 2020 16:17:53

US3822342

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:24:40
User entered 'Yes (Y)'	Krishna Shah (b) (4)	10 Dec 2020 16:18:03

US3822342

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:28:35
User entered 'I'	System	10 Dec 2020 16:18:03

US3822342

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:39:16
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	27 Jan 2021 20:43:49

US3822342

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:39:16
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '5 Jan 2021'	Kelly Woodell (b) (4)	27 Jan 2021 20:43:49

US3822342

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:39:16
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4)	27 Jan 2021 20:43:49

US3822342

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:39:16
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	Kelly Woodell (b) (4)	27 Jan 2021 20:43:49

US3822342

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:39:16
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	27 Jan 2021 20:44:58

US3822342

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:39:16
User entered 'I'	System	27 Jan 2021 20:44:58

US3822342

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:39:16
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:10:35

US3822342

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:39:16
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User closed query 'Per GCL Lab Recon: SARS-CoV2: PPD GCL has a SARS sample dated 02 FEB 2021 under Illness Visit Day 1 which is missing in EDC. Please review and initiate an Illness visit using ADD EVENT button and update the SARS sample details in Illness visit folder under Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection form as EDC has provision to record SARS sample in Illness visit folder only. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 10:50:06
Query 'Per GCL Lab Recon: SARS-CoV2: PPD GCL has a SARS sample dated 02 FEB 2021 under Illness Visit Day 1 which is missing in EDC. Please review and initiate an Illness visit using ADD EVENT button and update the SARS sample details in Illness visit folder under Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection form as EDC has provision to record SARS sample in Illness visit folder only. Thank you. ' answered with 'DATA HAS BEEN ENTERED' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 21:14:32
User opened query 'Per GCL Lab Recon: SARS-CoV2: PPD GCL has a SARS sample dated 02 FEB 2021 under Illness Visit Day 1 which is missing in EDC. Please review and initiate an Illness visit using ADD EVENT button and update the SARS sample details in Illness visit folder under Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection form as EDC has provision to record SARS sample in Illness visit folder only. Thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 13:40:14
User entered '02 Feb 2021'	(b) (4), (b) (6)	03 Feb 2021 20:10:35

US3822342

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:39:16
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:10:35

US3822342

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:39:16
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:10:35

US3822342

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:39:16
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:10:39

US3822342

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:39:16
User entered 'I'	System	03 Feb 2021 20:10:39

US3822342

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:02:41
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 20:56:39
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:39:16
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 07:29:39
Query 'Data is required. Please complete.' answered with 'Data entered in error' (Site from System).	(b) (4), (b) (6)	16 Feb 2021 15:31:03
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Feb 2021 15:30:53
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 15:30:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 15:30:10

US3822342

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:02:41
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 20:56:39
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:39:16
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
	System	16 Feb 2021 15:30:53
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	16 Feb 2021 15:30:53
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 15:30:53
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Feb 2021 15:30:10
User entered '12 Feb 2021'	(b) (4), (b) (6)	16 Feb 2021 15:30:10

US3822342

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:02:41
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 20:56:39
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:39:16
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 15:30:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Feb 2021 15:30:10

US3822342

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:02:41
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 20:56:39
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:39:16
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:30:10

US3822342

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:39:16
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:47:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Feb 2021 07:29:46
Query 'Data is required. Please complete.' answered with 'Date entered in error' (Site from System).	(b) (4), (b) (6)	16 Feb 2021 15:31:17
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Feb 2021 15:31:09
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 15:31:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 15:29:40

US3822342

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:39:16
User entered '1'	System	17 Mar 2021 19:47:59
User entered empty.	System	16 Feb 2021 15:31:09
User entered '1'	System	16 Feb 2021 15:29:40

US3822342

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please confirm if visit was performed as other forms of this visit has data on it. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 10:29:20
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:46:56
Query 'Per CDM: Please confirm if visit was performed as other forms of this visit has data on it. Please review and update accordingly.' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:06:30
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 18:06:24
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 18:06:24
User opened query 'Per CDM: Please confirm if visit was performed as other forms of this visit has data on it. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 16:28:29
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 16:08:53
Query 'Data is required. Please complete.' answered with 'visit not conducted yet' (Site from System).	(b) (4), (b) (6)	22 Mar 2021 18:01:25
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 19:50:21
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 19:50:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 19:48:11

US3822342

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:46:56
Signature has been broken.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:06:24
User entered '20 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 18:06:24
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 16:08:59
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 19:50:21
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'Visit out of window. deviation noted. ' (Site from System).	(b) (4), (b) (6)	17 Mar 2021 19:48:39
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	17 Mar 2021 19:48:11
User entered '17 Mar 2021'	(b) (4), (b) (6)	17 Mar 2021 19:48:11

US3822342

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:46:56
Signature has been broken.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:06:24
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 18:06:24
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:50:21
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	17 Mar 2021 19:48:11

US3822342

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	22 Apr 2021 18:06:24
User entered empty.	System	17 Mar 2021 19:50:21
User entered 'VISIT4'	System	17 Mar 2021 19:48:11

US3822342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:46:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:06:37

US3822342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:46:56
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:06:37

US3822342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:46:56
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:06:37

US3822342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 18:06:37

US3822342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:46:56
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:06:37

US3822342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:46:56
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:06:37

US3822342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:46:56
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:06:37

US3822342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:46:56
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:06:37

US3822342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 18:06:37

US3822342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:46:56
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:06:37

US3822342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 18:06:37

US3822342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:46:56
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:06:37

US3822342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 18:06:37

US3822342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:46:56
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:06:37

US3822342

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 18:06:37

US3822342

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:57:53

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:46:56
Signature has been broken.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:06:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 18:06:47
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:23:45
Query 'Data is required. Please complete.' answered with 'visit not conducted yet' (Site from System).	(b) (4), (b) (6)	22 Mar 2021 14:12:53
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 19:50:09
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 19:50:09
User entered 'No (N)'	(b) (4), (b) (6)	17 Mar 2021 19:49:00

US3822342

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:57:53

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 19:49:00

US3822342

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:46:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:07:41

US3822342

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:46:56
User entered '20 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:07:41

US3822342

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:46:56
User entered '13:20'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:07:41

US3822342

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '20 Apr 2021 13:20'	System	22 Apr 2021 18:07:41

US3822342

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:46:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:07:46

US3822342

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 18:07:46

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:57:53

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '31 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:32:46

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:57:53

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '14:09'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:32:46

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:57:53

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:49
User entered '31 Jan 2021 14:09'	System	11 Feb 2021 20:32:46

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:57:53

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Safety Call (Safety Call)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:32:46

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:57:53

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:32:46

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:36:50

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	11 Feb 2021 20:37:02
User entered '31 Jan 2021' reason for change: Data Entry Error	System	11 Feb 2021 20:37:02
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	11 Feb 2021 20:36:50
User entered '31 Feb 2021' (non-conformant).	System	11 Feb 2021 20:36:50
	(b) (4), (b) (6)	11 Feb 2021 20:36:50

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:36:50

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:36:50

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User entered empty.	System	11 Feb 2021 20:36:50

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:36:50

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:36:50

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:36:50

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:36:50

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:36:50

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:36:50

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:36:50

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:36:50

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:36:50

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:36:50

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:36:50

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:36:50

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:36:50

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:36:50

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:36:50

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:36:50

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:36:50

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Day 2 (Day 2)' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 20:40:13
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 20:37:02

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Feb 2021 20:40:13
User entered '1 Feb 2021' reason for change: Data Entry Error	System	11 Feb 2021 20:40:13
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Feb 2021 20:40:13
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 20:37:02

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 20:40:13
User entered '0'	(b) (4), (b) (6)	11 Feb 2021 20:37:02

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:37:02

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User entered empty.	System	11 Feb 2021 20:37:02

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:37:02

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 20:40:13
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 20:37:02

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 20:40:13
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 20:37:02

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 20:40:13
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 20:37:02

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 20:40:13
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 20:37:02

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 20:40:13
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 20:37:02

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 20:40:13
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 20:37:02

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 20:40:13
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 20:37:02

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 20:40:13
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 20:37:02

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 20:40:13
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 20:37:02

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 20:40:13
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 20:37:02

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 20:40:13
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 20:37:02

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 20:40:13
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 20:37:02

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 20:40:13
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 20:37:02

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 20:40:13
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 20:37:02

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 20:40:13
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 20:37:02

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 20:40:13
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 20:37:02

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:41:29

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '2 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:41:29

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:41:29

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:41:29

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User entered '%'	System	11 Feb 2021 20:41:29

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '98.8' F	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:41:29

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:41:29

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:41:29

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:41:29

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:41:29

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:41:29

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:41:29

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:41:29

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:41:29

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:41:29

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:41:29

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:41:29

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:41:29

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:41:29

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:41:29

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:41:29

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:41:29

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:42:22

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '3 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:42:22

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:42:22

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:42:22

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User entered empty.	System	11 Feb 2021 20:42:22

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:42:22

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:42:22

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:42:22

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:42:22

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:42:22

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:42:22

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:42:22

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:42:22

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:42:22

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:42:22

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:42:22

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:42:22

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:42:22

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:42:22

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:42:22

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:42:22

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:42:22

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:57:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:08

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:57:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '4 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:08

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:57:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:08

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:57:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:08

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:57:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User entered empty.	System	11 Feb 2021 20:43:08

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:57:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:08

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:57:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:08

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:57:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:08

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:57:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:08

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:57:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:08

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:57:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:08

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:57:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:08

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:57:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:08

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:57:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:08

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:57:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:08

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:57:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:08

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:57:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:08

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:57:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:08

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:57:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:08

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:57:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:08

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:57:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:08

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:57:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:45:55
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:43:08

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:57:53

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:46:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '2 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:14:04

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:57:53

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:46:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:14:04

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:57:53

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:46:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:14:04

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:57:53

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:46:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '2 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:14:04

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:57:53

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:46:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	11 Feb 2021 21:14:04

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:57:53

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:46:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:14:04

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:57:53

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:46:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:14:04

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:57:53

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:46:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:14:04

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:57:53

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:46:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:14:04

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:57:53

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:46:00
User entered '0'	System	11 Feb 2021 21:14:04

US3822342

Folder: Covid-19 Assessment 31 Jan 2021

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:57:53

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:46:05
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:14:16

US3822342

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:57:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:20
User accepted default value 'Day 3 (Day 3)'	Kelly Woodell (b) (4) (b) (4)	19 Feb 2021 13:40:21

US3822342

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:57:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4)	
reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 14:25:10
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	19 Feb 2021 13:40:21
	(b) (4)	

US3822342

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:57:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 05FEB2021 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 05FEB2021 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'covid negative' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 08:28:42
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 14:25:42
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 05FEB2021 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). User entered '5 Feb 2021'	(b) (4), (b) (6)	25 Feb 2021 14:25:10
	(b) (4), (b) (6)	25 Feb 2021 14:23:29
	Kelly Woodell (b) (4) (b) (4)	19 Feb 2021 13:40:21

US3822342

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:57:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:20
User accepted default value 'Day 5 (Day 5)'	Kelly Woodell (b) (4) (b) (4)	19 Feb 2021 13:40:21

US3822342

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:57:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'NA (COVID-19 Negative) (NA)'	Kelly Woodell (b) (4)	19 Feb 2021 13:40:21

US3822342

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:57:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	Kelly Woodell (b) (4)	19 Feb 2021 13:40:21

US3822342

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:57:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:20
User accepted default value 'Day 7 (Day 7)'	Kelly Woodell (b) (4) (b) (4)	19 Feb 2021 13:40:21

US3822342

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:57:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'NA (COVID-19 Negative) (NA)'	Kelly Woodell (b) (4)	19 Feb 2021 13:40:21

US3822342

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:57:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	Kelly Woodell (b) (4)	19 Feb 2021 13:40:21

US3822342

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:57:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:20
User accepted default value 'Day 9 (Day 9)'	Kelly Woodell (b) (4) (b) (4)	19 Feb 2021 13:40:21

US3822342

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:57:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'NA (COVID-19 Negative) (NA)'	Kelly Woodell (b) (4)	19 Feb 2021 13:40:21

US3822342

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:57:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	Kelly Woodell (b) (4)	19 Feb 2021 13:40:21

US3822342

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:57:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:20
User accepted default value 'Day 14 (Day 14)'	Kelly Woodell (b) (4) (b) (4)	19 Feb 2021 13:40:21

US3822342

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:57:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'NA (COVID-19 Negative) (NA)'	Kelly Woodell (b) (4)	19 Feb 2021 13:40:21

US3822342

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:57:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	Kelly Woodell (b) (4)	19 Feb 2021 13:40:21

US3822342

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:57:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:20
User accepted default value 'Day 21 (Day 21)'	Kelly Woodell (b) (4) (b) (4)	19 Feb 2021 13:40:21

US3822342

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:57:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'NA (COVID-19 Negative) (NA)'	Kelly Woodell (b) (4)	19 Feb 2021 13:40:21

US3822342

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:57:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	Kelly Woodell (b) (4)	19 Feb 2021 13:40:21

US3822342

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:57:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:20
User accepted default value 'Day 28 (Day 28)'	Kelly Woodell (b) (4) (b) (4)	19 Feb 2021 13:40:21

US3822342

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:57:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'NA (COVID-19 Negative) (NA)'	Kelly Woodell (b) (4)	19 Feb 2021 13:40:21

US3822342

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:57:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	Kelly Woodell (b) (4)	19 Feb 2021 13:40:21

US3822342

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:34:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:11:41

US3822342

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:34:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '2 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:11:41

US3822342

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:34:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:11:41

US3822342

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:34:41
User entered 'SICKD1'	System	11 Feb 2021 21:11:41

US3822342

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:34:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:12:22

US3822342

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:34:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '2 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:12:22

US3822342

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:34:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '13:32'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:12:22

US3822342

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:34:49
User entered '2 Feb 2021 13:32'	System	11 Feb 2021 21:12:22

US3822342

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:34:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:12:22
DataPoint set to visible.	System	11 Feb 2021 21:11:41

US3822342

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:34:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:12:22
DataPoint set to visible.	System	11 Feb 2021 21:11:41

US3822342

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:34:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	11 Feb 2021 21:12:30
User entered '98.8' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 21:12:30
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Feb 2021 21:12:22
User entered '98.8' (non-conformant).	(b) (4), (b) (6)	11 Feb 2021 21:12:22

US3822342

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:34:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:12:22

US3822342

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:34:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:12:22

US3822342

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:34:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '96'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:12:22

US3822342

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:34:49
User entered 'bpm'	System	11 Feb 2021 21:12:22

US3822342

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:34:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '24'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:12:22

US3822342

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:34:49
User entered 'breaths/min'	System	11 Feb 2021 21:12:22

US3822342

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:34:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '152'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:12:22

US3822342

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:34:49
User entered 'mmHg'	System	11 Feb 2021 21:12:22

US3822342

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:34:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '89'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:12:22

US3822342

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:34:49
User entered 'mmHg'	System	11 Feb 2021 21:12:22

US3822342

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:34:49

US3822342

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:34:49

US3822342

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:57:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:34:58
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:12:38

US3822342

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:57:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:34:58
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '2 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:12:38

US3822342

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:57:53

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:05
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:12:54

US3822342

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:57:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:35:05
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '2 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:12:54

US3822342

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

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	06 Jan 2021 15:39:01
	(b) (4)	

US3822342

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

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '5 Jan 2021'	Kelly Woodell (b) (4)	06 Jan 2021 15:39:01
	(b) (4)	

US3822342

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

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4)	06 Jan 2021 15:39:01
	(b) (4)	

US3822342

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

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'UNBLND_DECIDE'	System	06 Jan 2021 15:39:01

US3822342

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

Form: Unblinding

Generated On: 10 Jun 2021 09:57:53

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '05 Jan 2021'	Kelly Woodell (b) (4)	06 Jan 2021 15:39:18
	(b) (4)	

US3822342

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

Form: Unblinding

Generated On: 10 Jun 2021 09:57:53

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 20:22:58
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:15:29

US3822342

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

Form: Unblinding

Generated On: 10 Jun 2021 09:57:53

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	06 Jan 2021 15:39:18
	(b) (4)	

US3822342

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

Form: Unblinding

Generated On: 10 Jun 2021 09:57:53

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
	(b) (4)	
	(b) (4), (b) (6)	
	(b) (4)	
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:46:56
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 19:29:02
	(b) (4), (b) (6)	
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 19:29:02
	(b) (4), (b) (6)	
User closed query '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.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 15:37:22
	(b) (4)	
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
	(b) (4)	
Query '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.' answered with 'Query Resolved' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 20:23:17
	(b) (4)	
User entered 'Amendment 5 (Amendment 5)'	(b) (4), (b) (6)	08 Apr 2021 20:22:58
	(b) (4)	
User opened query '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.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 12:11:21
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:15:29

US3822342

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

Form: Unblinding

Generated On: 10 Jun 2021 09:57:53

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:46:56
	(b) (4)	
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4), (b) (6)	23 Apr 2021 11:18:22
User closed query 'Per CDM RQ: Response noted. However, this field is the date of unblinding in IRT. Please reconcile. Thank you' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 11:18:21
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'Subject was scheduled for the visit prior to being unblinded. The subject was unblinded the evening prior to the their scheduled visit. They were not notified of their randomization assignment until after signing the amendment 6 ICF and requesting to be unblinded.' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 19:30:34
Query 'Per CDM RQ: Response noted. However, this field is the date of unblinding in IRT. Please reconcile. Thank you' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 19:30:30
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	19 Apr 2021 19:29:02
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 19:29:02
User entered '04 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 19:29:02
User opened query 'Per CDM RQ: Response noted. However, this field is the date of unblinding in IRT. Please reconcile. Thank you' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 15:37:30
User closed query 'Per CDM, per Sponsor Review: Per IRT, subject was unblinded on 04JAN2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 15:37:30
Query 'Per CDM, per Sponsor Review: Per IRT, subject was unblinded on 04JAN2021. Please review and reconcile.' answered with 'Subject in clinic unblinding visit was 05JAN2021' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 20:23:35

US3822342

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

Form: Unblinding

Generated On: 10 Jun 2021 09:57:53

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'Per CDM, per Sponsor Review: Per IRT, subject was unblinded on 04JAN2021. Please review and reconcile.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4)	08 Apr 2021 16:19:41
	Christina Kennelly (b) (4) (b) (4)	02 Apr 2021 22:13:42
User entered '05 Jan 2021'	Kelly Woodell (b) (4) (b) (4)	06 Jan 2021 15:39:18

US3822342

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

Form: Unblinding

Generated On: 10 Jun 2021 09:57:53

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Placebo (Placebo)'	Kelly Woodell (b) (4)	06 Jan 2021 15:39:18
	(b) (4)	

US3822342

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

Form: Unblinding

Generated On: 10 Jun 2021 09:57:53

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 13:41:01
User entered 'Placebo (Placebo)'	Kelly Woodell (b) (4)	06 Jan 2021 15:39:18
	(b) (4)	

US3822342

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

Form: Unblinding

Generated On: 10 Jun 2021 09:57:53

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 13:41:01
User entered 'Placebo (Placebo)'	Kelly Woodell (b) (4)	06 Jan 2021 15:39:18
	(b) (4)	

US3822342

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

Form: Unblinding

Generated On: 10 Jun 2021 09:57:53

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	06 Jan 2021 15:39:18
	(b) (4)	

US3822342

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

Form: Unblinding

Generated On: 10 Jun 2021 09:57:53

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'I'	System	06 Jan 2021 15:39:18

US3822342

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

Form: Unblinding

Generated On: 10 Jun 2021 09:57:53

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'I'	System	06 Jan 2021 15:39:18

US3822342

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:57:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '70' in	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:57:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '196.0' lb	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:57:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered '28.18187'	System	06 Jan 2021 15:40:58
DataPoint set to visible.	System	06 Jan 2021 15:39:18

US3822342

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:57:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '70' in	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:57:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '196.0' lb	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:57:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered '28.18187'	System	06 Jan 2021 15:40:58
DataPoint set to visible.	System	06 Jan 2021 15:39:18

US3822342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User accepted default value 'Pre-Dose (PREDOSE)'	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '5 Jan 2021'	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '11:19'	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered '5 Jan 2021 11:19'	System	06 Jan 2021 15:40:58

US3822342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '97.2' F	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Oral (Oral)'	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered empty.	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '59'	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'bpm'	System	06 Jan 2021 15:40:58

US3822342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '14'	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'breaths/min'	System	06 Jan 2021 15:40:58

US3822342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '132'	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'mmHg'	System	06 Jan 2021 15:40:58

US3822342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '78'	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'mmHg'	System	06 Jan 2021 15:40:58

US3822342

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:57:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '70' in	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:57:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '196.0' lb	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:57:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered '28.18187'	System	06 Jan 2021 15:40:58
DataPoint set to visible.	System	06 Jan 2021 15:39:18

US3822342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User accepted default value 'Post-Dose (POSTDOSE)'	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '5 Jan 2021'	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '12:41'	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered '5 Jan 2021 12:41'	System	06 Jan 2021 15:40:58

US3822342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '97.7' F	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Oral (Oral)'	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered empty.	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '57'	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'bpm'	System	06 Jan 2021 15:40:58

US3822342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '18'	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'breaths/min'	System	06 Jan 2021 15:40:58

US3822342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '138'	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'mmHg'	System	06 Jan 2021 15:40:58

US3822342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '82'	Kelly Woodell (b) (4)	06 Jan 2021 15:40:58
	(b) (4)	

US3822342

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'mmHg'	System	06 Jan 2021 15:40:58

US3822342

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:57:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	06 Jan 2021 15:41:10
	(b) (4)	

US3822342

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:57:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '5 Jan 2021'	Kelly Woodell (b) (4)	06 Jan 2021 15:41:10
	(b) (4)	

US3822342

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

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	06 Jan 2021 15:41:25
	(b) (4)	

US3822342

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

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered empty.	Kelly Woodell (b) (4)	06 Jan 2021 15:41:25
	(b) (4)	

US3822342

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

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered empty.	Kelly Woodell (b) (4)	06 Jan 2021 15:41:25
	(b) (4)	

US3822342

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

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'mRNA-1273'	System	06 Jan 2021 15:41:25
DataPoint set to visible.	System	06 Jan 2021 15:39:18

US3822342

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

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '5 Jan 2021'	Kelly Woodell (b) (4)	06 Jan 2021 15:41:25
	(b) (4)	

US3822342

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

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '12:03'	Kelly Woodell (b) (4)	06 Jan 2021 15:41:25
	(b) (4)	

US3822342

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

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered '5 Jan 2021 12:03'	System	06 Jan 2021 15:41:25

US3822342

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

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Right Arm (RIGHT ARM)'	Kelly Woodell (b) (4)	06 Jan 2021 15:41:25
	(b) (4)	

US3822342

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

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'ONCE'	System	06 Jan 2021 15:41:25

US3822342

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

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'INTRAMUSCULAR'	System	06 Jan 2021 15:41:25

US3822342

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	06 Jan 2021 15:41:35
	(b) (4)	

US3822342

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '5 Jan 2021'	Kelly Woodell (b) (4)	06 Jan 2021 15:41:35
	(b) (4)	

US3822342

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '11:24'	Kelly Woodell (b) (4)	06 Jan 2021 15:41:35
	(b) (4)	

US3822342

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered '5 Jan 2021 11:24'	System	06 Jan 2021 15:41:35

US3822342

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	06 Jan 2021 15:41:43
	(b) (4)	

US3822342

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:57:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '5 Jan 2021'	Kelly Woodell (b) (4)	06 Jan 2021 15:41:43
	(b) (4)	

US3822342

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:57:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '11:30'	Kelly Woodell (b) (4)	06 Jan 2021 15:41:43
	(b) (4)	

US3822342

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:57:53

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered '5 Jan 2021 11:30'	System	06 Jan 2021 15:41:43

US3822342

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

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	06 Jan 2021 15:41:50
	(b) (4)	

US3822342

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

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'I'	System	06 Jan 2021 15:41:50

US3822342

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 12:46:51

US3822342

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '12 Jan 2021'	(b) (4), (b) (6)	26 Feb 2021 12:46:51

US3822342

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Feb 2021 12:46:51

US3822342

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 12:46:51

US3822342

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 12:46:55

US3822342

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'I'	System	26 Feb 2021 12:46:55

US3822342

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'I'	System	26 Feb 2021 12:46:55
DataPoint set to visible.	System	26 Feb 2021 12:46:55

US3822342

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 12:48:06

US3822342

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User closed query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	01 Mar 2021 10:24:13
Query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' answered with 'Day 29 22 days out of window. Deviation noted.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 12:50:52
User opened query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	26 Feb 2021 12:48:06
User entered '25 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 12:48:06

US3822342

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Feb 2021 12:48:06

US3822342

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'OLD29'	System	26 Feb 2021 12:48:06

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '25 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '10:19'	(b) (4), (b) (6)	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered '25 Feb 2021 10:19'	System	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '97.2' F	(b) (4), (b) (6)	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '58'	(b) (4), (b) (6)	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'bpm'	System	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '20'	(b) (4), (b) (6)	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'breaths/min'	System	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '118'	(b) (4), (b) (6)	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'mmHg'	System	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '74'	(b) (4), (b) (6)	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:57:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'mmHg'	System	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '25 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '11:10'	(b) (4), (b) (6)	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered '25 Feb 2021 11:10'	System	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '97.8' F	(b) (4), (b) (6)	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '58'	(b) (4), (b) (6)	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'bpm'	System	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '15'	(b) (4), (b) (6)	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'breaths/min'	System	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '125'	(b) (4), (b) (6)	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'mmHg'	System	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '70'	(b) (4), (b) (6)	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:57:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'mmHg'	System	26 Feb 2021 12:52:01

US3822342

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:57:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 12:52:08

US3822342

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:57:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 12:52:08

US3822342

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 12:52:25

US3822342

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 12:52:25

US3822342

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 12:52:25

US3822342

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'mRNA-1273'	System	26 Feb 2021 12:52:25
DataPoint set to visible.	System	26 Feb 2021 12:46:55

US3822342

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '25 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 12:52:25

US3822342

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '10:40'	(b) (4), (b) (6)	26 Feb 2021 12:52:25

US3822342

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered '25 Feb 2021 10:40'	System	26 Feb 2021 12:52:25

US3822342

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	26 Feb 2021 12:52:25

US3822342

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'ONCE'	System	26 Feb 2021 12:52:25

US3822342

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:57:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'INTRAMUSCULAR'	System	26 Feb 2021 12:52:25

US3822342

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 12:52:27

US3822342

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'I'	System	26 Feb 2021 12:52:27

US3822342

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 19:55:25

US3822342

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '05 Mar 2021'	(b) (4), (b) (6)	08 Mar 2021 19:55:25

US3822342

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Mar 2021 19:55:25

US3822342

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:57:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 19:55:25

US3822342

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 19:55:30

US3822342

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:57:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'I'	System	08 Mar 2021 19:55:30

US3822342

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 19:50:40

US3822342

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	25 Mar 2021 18:24:03
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with '5 DAYS OUT OF WINDOW. DEVIATION NOTED' (Site from System).	(b) (4), (b) (6)	22 Mar 2021 13:34:26
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	17 Mar 2021 19:50:40
User entered '17 Mar 2021'	(b) (4), (b) (6)	17 Mar 2021 19:50:40

US3822342

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	17 Mar 2021 19:50:40

US3822342

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:57:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered 'OLD57'	System	17 Mar 2021 19:50:40

US3822342

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	17 Mar 2021 19:51:03

US3822342

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 19:51:03

US3822342

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 19:51:03

US3822342

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered empty.	System	17 Mar 2021 19:51:03

US3822342

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 19:51:03

US3822342

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 19:51:03

US3822342

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 19:51:03

US3822342

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 19:51:03

US3822342

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered empty.	System	17 Mar 2021 19:51:03

US3822342

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 19:51:03

US3822342

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered empty.	System	17 Mar 2021 19:51:03

US3822342

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 19:51:03

US3822342

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered empty.	System	17 Mar 2021 19:51:03

US3822342

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 19:51:03

US3822342

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered empty.	System	17 Mar 2021 19:51:03

US3822342

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49

US3822342

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:57:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49

US3822342

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:57:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	17 Mar 2021 19:51:08

US3822342

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:57:53

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 19:51:08

US3822342

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 19:51:45

US3822342

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '17 Mar 2021'	(b) (4), (b) (6)	17 Mar 2021 19:51:45

US3822342

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '13:28'	(b) (4), (b) (6)	17 Mar 2021 19:51:45

US3822342

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:57:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:43:49
User entered '17 Mar 2021 13:28'	System	17 Mar 2021 19:51:45

US3822342

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:57:53

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:14:01
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:02:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:53
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 16:18:11

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User closed query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 13:29:07
Query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable.' answered with 'This was post injection. Resolved within minutes. No evidence this is related to underlying medical history. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 19:01:26
User opened query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable.' (Site from DM).	(b) (4), (b) (6)	14 Feb 2021 17:25:30
User coded data point as SOC: Vascular disorders, HLGT: Decreased and nonspecific blood pressure disorders and shock, HLT: Vascular hypotensive disorders, PT: Hypotension, LLT: Low blood pressure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Dec 2020 18:38:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Dec 2020 18:38:50
Data point term sent to Coder	System	10 Dec 2020 16:20:23
User entered 'dizzy and sweaty with low blood pressure'	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered 'No (N)'	Krishna Shah (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered 'No (N)'	(b) (4) Krishna Shah (b) (4) (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered 'No (N)'	(b) (4) Krishna Shah (b) (4) (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered '9 Oct 2020'	Krishna Shah (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 08:09:49
Query 'Data is required. Please provide.' answered with 'unknown ' (Site from System).	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 16:19:38
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Dec 2020 16:19:28
User entered empty.	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
User entered empty.	System	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered 'No (N)'	(b) (4) Krishna Shah (b) (4) (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered '9 Oct 2020'	Krishna Shah (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 08:09:52
Query 'Data is required. Please provide.' answered with 'unknown ' (Site from System).	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 16:19:43
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Dec 2020 16:19:28
User entered empty.	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
User entered empty.	System	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Krishna Shah (b) (4) (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered 'No (N)'	Krishna Shah (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered '0'	(b) (4) Krishna Shah (b) (4) (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered '0'	(b) (4) Krishna Shah (b) (4) (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered '0'	Krishna Shah (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered empty.	Krishna Shah (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered empty.	Krishna Shah (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered empty.	(b) (4) Krishna Shah (b) (4) (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered empty.	Krishna Shah (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered '0'	Krishna Shah (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered '0'	(b) (4) Krishna Shah (b) (4) (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered '0'	(b) (4) Krishna Shah (b) (4) (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered 'Related (RELATED)'	Krishna Shah (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered 'Not Related (NOT RELATED)'	(b) (4) Krishna Shah (b) (4) (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Krishna Shah (b) (4) (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered 'I'	(b) (4) Krishna Shah (b) (4) (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered '0'	(b) (4) Krishna Shah (b) (4) (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered '0'	(b) (4) Krishna Shah (b) (4) (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Krishna Shah (b) (4) (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered empty.	Krishna Shah (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered empty.	Krishna Shah (b) (4)	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
User entered '0'	System	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31
User entered '0'	System	10 Dec 2020 16:19:28

US3822342

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:57:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:31

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
DataPoint Verified.	(b) (4)	05 Mar 2021 15:34:01
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:51:14
User entered	System	09 Feb 2021 18:40:42
'USA-US126-2021-mRNA-1273-P301000004'		
User entered 'New'	(b) (4), (b) (6)	09 Feb 2021 18:40:42

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:34:03
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pleural effusion, LLT: Pleural effusion - version MedDRA\\23.0.	Coder Import (b) (4)	08 Feb 2021 20:04:42
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Feb 2021 20:04:42
	(b) (4)	
Data point term sent to Coder	System	08 Feb 2021 20:03:28
User entered 'Right Pleural Effusion'	(b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:08
User entered 'No (N)'	(b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:09
User entered 'No (N)'	(b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:12
User entered '05 Feb 2021'	(b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:14
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	08 Feb 2021 20:03:12
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Feb 2021 20:03:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 20:03:12
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Feb 2021 20:02:38
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	08 Feb 2021 20:02:38
User entered 'UN:UN' (non-conformant).	(b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Feb 2021 20:03:12
User entered '05 Feb 2021 UN:UN' (non-conformant).	System	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 17:18:03
User signature succeeded.	Christina Kennelly (b) (4)	30 Apr 2021 12:57:10
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' answered with 'Updated' (Site from Safety).	Kelly Woodell (b) (4)	30 Apr 2021 12:10:48
DataPoint Un-verified.	Kelly Woodell (b) (4)	30 Apr 2021 12:07:22
Signature has been broken.	Kelly Woodell (b) (4)	30 Apr 2021 12:07:22
User entered 'No (N)' reason for change: Data Entry Error	Kelly Woodell (b) (4)	30 Apr 2021 12:07:22
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 14:04:57
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:46:56
Query 'PV Query: Please clarify event end date of 15 Feb 2021 as chest x-ray on 22 Mar 2021 showed that the pleural effusion was still ongoing. ' canceled (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 20:41:41
User opened query 'PV Query: Please clarify event end date of 15 Feb 2021 as chest x-ray on 22 Mar 2021 showed that the pleural effusion was still ongoing. ' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 20:39:10

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:43
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 20:19:32
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 20:19:32
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	09 Apr 2021 13:51:41
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 13:51:41
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 13:51:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 13:51:41
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	09 Apr 2021 13:51:20
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 17:45:57
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Per virtual visit with provider on 4/1 this is still ongoing' (Site from Safety).	Kelly Woodell (b) (4)	07 Apr 2021 20:37:05
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 12:43:09
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:34:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	30 Apr 2021 12:57:10
DataPoint Un-verified.	(b) (4)	
	Kelly Woodell (b) (4)	30 Apr 2021 12:07:22
	(b) (4)	
Signature has been broken.	Kelly Woodell (b) (4)	30 Apr 2021 12:07:22
	(b) (4)	
User entered '08 Feb 2021' reason for change: Data Entry Error	Kelly Woodell (b) (4)	30 Apr 2021 12:07:22
	(b) (4)	
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 18:18:38
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:46:56
	(b) (4)	
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 'Per your last query and patient medical records, chest xray on 22MAR2021 shows that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 14:32:13
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 20:43:51
User closed query 'PV Query: Please clarify event end date of 15 Feb 2021 as chest x-ray on 22 Mar 2021 showed that the pleural effusion was still ongoing. ' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 17:45:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:46
Query 'PV Query: Please clarify event end date of 15 Feb 2021 as chest x-ray on 22 Mar 2021 showed that the pleural effusion was still ongoing. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 20:20:44
User closed query 'Outcome is Recovered/Resolved, System Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	21 Apr 2021 20:20:06
Query 'Outcome is Recovered/Resolved, System Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	21 Apr 2021 20:20:06

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 20:19:32
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 20:19:32
User opened query 'PV Query: Please clarify event end date of 15 Feb 2021 as chest x-ray on 22 Mar 2021 showed that the pleural effusion was still ongoing. ' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	19 Apr 2021 13:06:01
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System). DataPoint Un-verified.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
Signature has been broken.	(b) (4)	09 Apr 2021 13:51:20
User entered '15 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 13:51:20
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). User signature succeeded.	System	09 Apr 2021 13:50:56
DataPoint Verified.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	(b) (4), (b) (6)	05 Mar 2021 15:34:18
	System	22 Feb 2021 14:23:54
	System	22 Feb 2021 14:23:54

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'Outcome is Recovered/Resolved, System Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). User entered empty.	(b) (4), (b) (6)	22 Feb 2021 14:23:33
		08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:19
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 14:03:57
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)	16 Feb 2021 15:30:21
User entered empty.	System	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:21
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:34:28
User entered '0'	(b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:30
User entered '0'	(b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:35
User entered 'I'	(b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:36
User entered '05 Feb 2021'	(b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
Query 'PV Query: Please resend hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 19:10:28
User opened query 'PV Query: Please resend hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 19:09:21
User closed query '	(b) (4), (b) (6)	08 Mar 2021 19:09:21
PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).		
Query '	Kelly Woodell (b) (4) (b) (4)	05 Mar 2021 15:48:08
PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'This has been submitted' (Site from Safety).		
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:34:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query ' PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety). User entered '07 Feb 2021'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Mar 2021 16:48:06
	(b) (4), (b) (6) (b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:42
User entered 'No (N)'	(b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:44
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:48
User entered '0'	(b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:50
User entered '0'	(b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:52
User entered '0'	(b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:54
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:34:55
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 05 Jan 2021, then event occurred on 05 Feb 2021 and received second dose on 25 Feb 2021). Please consider updating action taken to "None". If not, please clarify.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) Christina Kennelly (b) (4)	30 Apr 2021 17:18:22 30 Apr 2021 12:57:10
Query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 05 Jan 2021, then event occurred on 05 Feb 2021 and received second dose on 25 Feb 2021). Please consider updating action taken to "None". If not, please clarify.' answered with 'Updated' (Site from Safety). DataPoint Un-verified.	Kelly Woodell (b) (4) Kelly Woodell (b) (4)	30 Apr 2021 12:11:07 30 Apr 2021 12:07:22
Signature has been broken.	Kelly Woodell (b) (4)	30 Apr 2021 12:07:22
User entered 'None (NONE)' reason for change: Data Entry Error	Kelly Woodell (b) (4)	30 Apr 2021 12:07:22
User opened query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 05 Jan 2021, then event occurred on 05 Feb 2021 and received second dose on 25 Feb 2021). Please consider updating action taken to "None". If not, please clarify.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 14:03:21 21 Apr 2021 16:47:51
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User closed query 'PV Query: As the last dose of Placebo was given on 08 Oct 2020, please update the action taken with study drug from dose delayed to not applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 16:19:41
Query 'PV Query: As the last dose of Placebo was given on 08 Oct 2020, please update the action taken with study drug from dose delayed to not applicable.' answered with 'Updated' (Site from Safety). DataPoint Un-verified.	Kelly Woodell (b) (4) Kelly Woodell (b) (4)	24 Mar 2021 15:10:13 24 Mar 2021 15:10:07

PRODUCTION RELEASE (v12.003
EAB) (1725)

2188 of 2654

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Kelly Woodell (b) (4)	24 Mar 2021 15:10:07
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:34:57
User opened query 'PV Query: As the last dose of	(b) (4), (b) (6)	02 Mar 2021 16:46:31
Placebo was given on 08 Oct 2020, please update the		
action taken with study drug from dose delayed to not		
applicable.' (Site from Safety).		
User entered 'Dose Delayed (DOSE DELAYED)'	(b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:35:01
User entered '0'	(b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:35:06
User entered 'I'	(b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:35:08
User entered 'I'	(b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) (b) (4)	30 Apr 2021 17:18:39
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'Updated' (Site from Safety). DataPoint Un-verified.	Christina Kennelly (b) (4) (b) (4) Kelly Woodell (b) (4) (b) (4)	30 Apr 2021 12:57:10 30 Apr 2021 12:13:25
Signature has been broken.	Kelly Woodell (b) (4) (b) (4)	30 Apr 2021 12:07:22 30 Apr 2021 12:07:22
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	30 Apr 2021 12:07:22
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) Christina Kennelly (b) (4) (b) (4)	29 Apr 2021 14:05:22 23 Apr 2021 14:46:56
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 20:20:06
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 20:20:06
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 20:20:06

PRODUCTION RELEASE (v12.003
EAB) (1725)

2193 of 2654

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:47:24
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 19:20:49
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Data updated' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 13:51:48
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 13:50:56
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 13:50:56
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 13:50:56
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 18:13:43
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:19:46
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Per chest x-ray 3/22/2021 AE is ongoing' (Site from Safety).	Kelly Woodell (b) (4) (b) (4)	24 Mar 2021 15:15:53
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:35:13
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 16:55:21
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 15:39:04

PRODUCTION RELEASE (v12.003
EAB) (1725)

2194 of 2654

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Per record this is still ongoing' (Site from Safety).	Kelly Woodell (b) (4)	23 Feb 2021 18:47:35
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 14:23:54
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 14:23:33
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	16 Feb 2021 15:30:16
		08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	30 Apr 2021 12:57:10
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	(b) (4)	
DataPoint Un-verified.	System	30 Apr 2021 12:15:03
Signature has been broken.	Kelly Woodell (b) (4)	30 Apr 2021 12:15:03
User entered 'Per medical record right pleural effusion still ongoing.' reason for change: Data Entry Error	(b) (4)	
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	Kelly Woodell (b) (4)	30 Apr 2021 12:15:03
User signature succeeded.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:35:15
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:35:17
Query 'PV Query: Please provide the cause of the pleural effusion.' canceled (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 16:54:50
Query 'PV Query: Please provide date of negative COVID-19 test.' canceled (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 16:54:45
User opened query 'PV Query: Please provide the cause of the pleural effusion.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 16:46:09
User opened query 'PV Query: Please provide date of negative COVID-19 test.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 16:46:01
User closed query 'PV Query: Please provide the cause of the pleural effusion.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 13:49:30
Query 'PV Query: Please provide the cause of the pleural effusion.' answered with 'patient states that MD does not know the cause of pleural effusion' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 15:10:22
User closed query 'PV Query: Please provide date of negative COVID-19 test.' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 15:39:00
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 15:38:57
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Added' (Site from Safety).	Kelly Woodell (b) (4)	23 Feb 2021 18:58:51
Query 'PV Query: Please provide date of negative COVID-19 test.' answered with 'COVID 19 test was done through the study labs. They are in the portal.' (Site from Safety).	Kelly Woodell (b) (4)	23 Feb 2021 18:51:16

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 15:30:54
User opened query 'PV Query: Please provide the cause of the pleural effusion.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 15:30:32
User opened query 'PV Query: Please provide date of negative COVID-19 test.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 15:30:12
User entered 'The subject was tested for COVID-19 through the trial and found to be negative. He was having difficulty breathing and presented to the emergency room on 05Feb2021. He was found to have a pleural effusion which was drained. The subject was started on doxycycline and discharged on 07Feb2021.'	(b) (4), (b) (6)	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:57:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Feb 2021 20:02:38

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User closed query 'Per DM CLR: Please confirm the AE term "Worsening OVERACTIVE BLADDER", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "worsening" from this event. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 12:26:12
User coded data point as SOC: Renal and urinary disorders, HLT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary incontinence, LLT: Urinary incontinence aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 10:03:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 10:03:42
User signature succeeded.	Christina Kennelly (b) (4) (b) (4)	26 Mar 2021 18:57:42
Data point term sent to Coder	System	26 Mar 2021 18:04:01
Query 'Per DM CLR: Please confirm the AE term "Worsening OVERACTIVE BLADDER", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "worsening" from this event. ' answered with 'Term updated to per query' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	26 Mar 2021 18:03:13
Coding entries removed.	Kelly Woodell (b) (4) (b) (4)	26 Mar 2021 18:03:03
User entered 'WORSENING OF URINARY INCONTINENCE' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	26 Mar 2021 18:03:03
User opened query 'Per DM CLR: Please confirm the AE term "Worsening OVERACTIVE BLADDER", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "worsening" from this event. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 05:57:22

PRODUCTION RELEASE (v12.003
EAB) (1725)

2202 of 2654

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Myoneurogenic bladder disorders, PT: Hypertonic bladder, LLT: Overactive bladder - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 15:21:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 15:21:58
Data point term sent to Coder	System	23 Feb 2021 19:33:43
User entered 'WORSENING OF OVERACTIVE BLADDER'	(b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '1 Oct 2020' reason for change: Data Entry Error	System	23 Feb 2021 19:33:33
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	23 Feb 2021 19:33:33
User entered 'UN Oct 2020' (non-conformant).	System	23 Feb 2021 19:33:01
	(b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User closed query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 12:21:10
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
Query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' answered with 'Severity updated' (Site from DM).	Kelly Woodell (b) (4)	07 Apr 2021 20:40:15
Signature has been broken.	Kelly Woodell (b) (4)	07 Apr 2021 20:39:55
User entered 'Grade 2/Moderate (Grade 2/Moderate) reason for change: Data Entry Error	Kelly Woodell (b) (4)	07 Apr 2021 20:39:55
User opened query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 12:26:55
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 18:57:42
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:57:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Feb 2021 19:33:01

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User coded data point as SOC: Vascular disorders, HLTG: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 14:06:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 14:06:05
Data point term sent to Coder	System	09 Apr 2021 13:47:14
User entered 'Worsening of hypertension'	(b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
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)	09 Apr 2021 13:46:37
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 13:46:37
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	09 Apr 2021 13:46:18
User entered '00:00'	(b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
User entered empty.	System	09 Apr 2021 13:46:37
User entered '15 Dec 2020 00:00'	System	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	09 Apr 2021 13:47:13
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Apr 2021 13:47:13
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 13:47:13
Query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' answered with 'Data removed' (Site from System).	(b) (4), (b) (6)	09 Apr 2021 13:46:46
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Apr 2021 13:46:18
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	09 Apr 2021 13:46:18
User entered 'UN:UN' (non-conformant).	(b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
User entered empty.	System	09 Apr 2021 13:47:13
User entered '15 Dec 2020 UN:UN' (non-conformant).	System	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 13:47:13
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	09 Apr 2021 13:47:13
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	09 Apr 2021 13:46:18
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 13:47:13
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	09 Apr 2021 13:47:13
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	09 Apr 2021 13:46:18
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 13:47:13
User entered 'None (NONE)' reason for change:	System	09 Apr 2021 13:47:13
Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 13:47:13
User opened query 'Data is required. Please complete.' (Site from System).		
User entered empty.	System	09 Apr 2021 13:46:18
	(b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	09 Apr 2021 13:47:13
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 13:47:13
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Apr 2021 13:46:18
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 13:47:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	09 Apr 2021 13:47:13
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 13:46:18
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
User entered '0'	System	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34
User entered '0'	System	09 Apr 2021 13:46:18

US3822342

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:57:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:03:34

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:57:53

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:14:01
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:39:11

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Oct 2020 09:07:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 09:07:49
Data point term sent to Coder	System	30 Sep 2020 15:40:48
User entered 'Rosuvastatin'	(b) (4), (b) (6)	30 Sep 2020 15:39:57

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:39:57

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'HCL'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:39:57

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'UNK'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:39:57

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:39:57

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:39:57

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:39:57

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:39:57

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:39:57

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:39:57

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'UN UNK 2019'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:39:57

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:39:57

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:39:57

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:39:57

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:39:57

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 15:39:57

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 15:39:57

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 15:39:57

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Sep 2020 15:41:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:41:56
Data point term sent to Coder	System	30 Sep 2020 15:40:48
User entered 'Pantoprazole'	(b) (4), (b) (6)	30 Sep 2020 15:40:25

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:25

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'GERD'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:25

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '40'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:25

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:25

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:25

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:25

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:25

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:25

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:25

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'UN UNK 1970'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:25

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:25

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:25

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:25

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:25

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 15:40:25

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 15:40:25

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 15:40:25

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
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)	30 Sep 2020 15:42:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:42:58
Data point term sent to Coder	System	30 Sep 2020 15:41:51
User entered 'Amlodipine'	(b) (4), (b) (6)	30 Sep 2020 15:40:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'HTN'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '5'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'UN UNK 2005'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:40:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 15:40:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 15:40:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 15:40:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
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: ASA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Dec 2020 18:46:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:46:54
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	02 Dec 2020 20:43:34 02 Dec 2020 20:43:27
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: ASA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:42:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:42:59
Data point term sent to Coder User entered 'ASA'	System (b) (4), (b) (6)	30 Sep 2020 15:41:51 30 Sep 2020 15:41:24

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:41:24

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:53

Indication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User closed query 'Per DM CLR: Please review if this medication is given as a prophylaxis or a supplement. If given as a prophylaxis, please update ConMed reason to include the Medical Condition to support the prophylactic indication or if supplement, update Reason for Medication to reflect this information. Update ConMed eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 09:21:38
Query 'Per DM CLR: Please review if this medication is given as a prophylaxis or a supplement. If given as a prophylaxis, please update ConMed reason to include the Medical Condition to support the prophylactic indication or if supplement, update Reason for Medication to reflect this information. Update ConMed eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 20:43:33
User entered 'CARDIAC SUPPLEMENT - HEART ISSUES BEING MONITORED' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 20:43:27
User opened query 'Per DM CLR: Please review if this medication is given as a prophylaxis or a supplement. If given as a prophylaxis, please update ConMed reason to include the Medical Condition to support the prophylactic indication or if supplement, update Reason for Medication to reflect this information. Update ConMed eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 22:33:37
User entered 'Supplement'	(b) (4), (b) (6)	30 Sep 2020 15:41:24

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '81'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:41:24

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:41:24

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:41:24

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:41:24

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:41:24

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:41:24

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:41:24

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'UN UNK 2014'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:41:24

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:41:24

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:41:24

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:41:24

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:41:24

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 15:41:24

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 15:41:24

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 15:41:24

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: BISPHOSPHONATES, PRODUCT: ALENDRONATE SODIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Sep 2020 17:50:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 17:50:58
Data point term sent to Coder	System	30 Sep 2020 15:42:53
User entered 'Atendronate'	(b) (4), (b) (6)	30 Sep 2020 15:42:38

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:42:38

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Osteopenia'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:42:38

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '70'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:42:38

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:42:38

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:42:38

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'every week (QS)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:42:38

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:42:38

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:42:38

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:42:38

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '28 Feb 2019'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:42:38

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:42:38

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:42:38

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:42:38

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:42:38

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 15:42:38

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 15:42:38

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	30 Sep 2020 15:42:38

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:53

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: MIRABEGRON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Dec 2020 14:50:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Dec 2020 14:50:42
Data point term sent to Coder	System	02 Dec 2020 20:46:36
Coding entries removed.	(b) (4), (b) (6)	02 Dec 2020 20:45:37
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: MIRABEGRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:44:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:44:48
Data point term sent to Coder	System	30 Sep 2020 15:43:55
User entered 'Mirabegron'	(b) (4), (b) (6)	30 Sep 2020 15:43:23

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:43:23

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
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)	14 Dec 2020 09:23:20
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 'URINARY INCONTINENCE IS ADDED' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 20:45:53
User entered 'OVERACTIVE BLADDER - URINARY INCONTINENCE' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 20:45:37
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)	30 Nov 2020 22:33:56
User entered 'overactive bladder'	(b) (4), (b) (6)	30 Sep 2020 15:43:23

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '50'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:43:23

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:43:23

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:43:23

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:43:23

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:43:23

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:43:23

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:43:23

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'UN UNK 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:43:23

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:43:23

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:43:23

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:43:23

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:43:23

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 15:43:23

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 15:43:23

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 15:43:23

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:02
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: HEPATITIS VACCINES, PRODUCT: HEPATITIS B VACCINE, PRODUCTSYNONYM: HEP [HEPATITIS B VACCINE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Sep 2020 15:45:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:45:53
Data point term sent to Coder User entered 'Hep B'	System (b) (4), (b) (6)	30 Sep 2020 15:44:56 30 Sep 2020 15:44:11

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:02
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:44:11

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:02
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Vaccine'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:44:11

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:02
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'UNK'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:44:11

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:02
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:44:11

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:02
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:44:11

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:02
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:44:11

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:02
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:44:11

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:02
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	30 Sep 2020 15:44:11

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:02
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:44:11

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:02
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '16 Sep 2011'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:44:11

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:02
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:44:11

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:02
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:44:11

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:02
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '16 Sep 2011'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:44:11

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:02
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:44:11

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:02
User entered empty.	System	30 Sep 2020 15:44:11

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:02
User entered empty.	System	30 Sep 2020 15:44:11

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:02
User entered empty.	System	30 Sep 2020 15:44:11

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:06
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 12:54:55
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 12:54:55
User signature succeeded.	Christina Kennelly (b) (4) (b) (4)	02 Apr 2021 22:13:42
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)	30 Sep 2020 15:45:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:45:53
Data point term sent to Coder User entered 'Diphtheria, Tetanus, Pertussis'	System (b) (4), (b) (6)	30 Sep 2020 15:44:58 30 Sep 2020 15:44:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:06
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:44:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:06
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Vaccine'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:44:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:06
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'UNK'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:44:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:06
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:44:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:06
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:44:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:06
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:44:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:06
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:44:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:06
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:44:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:53

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:06
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:44:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:06
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '21 Apr 2014'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:44:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:06
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:44:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:06
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:44:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:06
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '21 Apr 2014'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:44:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:06
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:44:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:06
User entered empty.	System	30 Sep 2020 15:44:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:06
User entered empty.	System	30 Sep 2020 15:44:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:06
User entered empty.	System	30 Sep 2020 15:44:58

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:43
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE, PRODUCTSYNONYM: INFLUENZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 06:02:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 06:02:28
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 21:22:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 21:22:57
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE, PRODUCTSYNONYM: INFLUENZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:46:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:46:55
Data point term sent to Coder User entered 'Influenza'	System (b) (4), (b) (6)	30 Sep 2020 15:45:59 30 Sep 2020 15:45:33

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:43
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:45:33

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:43
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Vaccine'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:45:33

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:43
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'UNK'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:45:33

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:43
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:45:33

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:43
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:45:33

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:43
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:45:33

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:43
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:45:33

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:43
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:45:33

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:43
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:45:33

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:43
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '23 Aug 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:45:33

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:43
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:45:33

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:43
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:45:33

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:43
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '23 Aug 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:45:33

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:43
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:45:33

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:43
User entered empty.	System	30 Sep 2020 15:45:33

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:43
User entered empty.	System	30 Sep 2020 15:45:33

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:43
User entered empty.	System	30 Sep 2020 15:45:33

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
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.	(b) (4) Coder Import (b) (4) (b) (4)	30 Sep 2020 15:47:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:47:48
Data point term sent to Coder User entered 'Pneumococcal'	System (b) (4), (b) (6)	30 Sep 2020 15:47:01 30 Sep 2020 15:46:12

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:46:12

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Vaccine'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:46:12

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'UNK'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:46:12

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:46:12

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:46:12

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:46:12

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:46:12

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	30 Sep 2020 15:46:12

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:46:12

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '22 Jun 2009'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:46:12

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:46:12

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:46:12

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '22 Jun 2009'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:46:12

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:46:12

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:19
User entered empty.	System	30 Sep 2020 15:46:12

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:19
User entered empty.	System	30 Sep 2020 15:46:12

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:44:19
User entered empty.	System	30 Sep 2020 15:46:12

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:53

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: TROSPIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Mar 2021 08:52:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 08:52:44
User closed query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 11:24:52
Query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 19:31:47
Data point term sent to Coder	System	23 Feb 2021 19:31:42
Coding entries removed.	(b) (4), (b) (6)	23 Feb 2021 19:31:40
User entered 'TROSPIUM - WORSENING OF OVERACTIVE BLADDER' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 19:31:40
User opened query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 15:32:01

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: TROSPIMUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 11:38:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 11:38:21
Data point term sent to Coder	System	10 Dec 2020 16:29:32
User entered 'Tropium'	Krishna Shah (b) (4)	10 Dec 2020 16:28:53
	(b) (4)	

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'No (N)'	Krishna Shah (b) (4)	10 Dec 2020 16:28:53
	(b) (4)	

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'URINARY INCONTINENCE'	(b) (4) Krishna Shah (b) (4) (b) (4)	10 Dec 2020 16:28:53

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '60'	Krishna Shah (b) (4)	10 Dec 2020 16:28:53
	(b) (4)	

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'mg (mg)'	Krishna Shah (b) (4)	10 Dec 2020 16:28:53
	(b) (4)	

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered empty.	Krishna Shah (b) (4)	10 Dec 2020 16:28:53
	(b) (4)	

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'once daily (QD)'	(b) (4) Krishna Shah (b) (4) (b) (4)	10 Dec 2020 16:28:53

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered empty.	Krishna Shah (b) (4)	10 Dec 2020 16:28:53
	(b) (4)	

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Oral (ORAL)'	Krishna Shah (b) (4)	10 Dec 2020 16:28:53
	(b) (4)	

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) Krishna Shah (b) (4) (b) (4)	10 Dec 2020 16:28:53

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '1 Oct 2020'	Krishna Shah (b) (4)	10 Dec 2020 16:28:53
	(b) (4)	

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '0'	Krishna Shah (b) (4)	10 Dec 2020 16:28:53
	(b) (4)	

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'Yes (Y)'	Krishna Shah (b) (4)	10 Dec 2020 16:28:53
	(b) (4)	

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered empty.	Krishna Shah (b) (4)	10 Dec 2020 16:28:53
	(b) (4)	

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered 'No (N)'	Krishna Shah (b) (4)	10 Dec 2020 16:28:53
	(b) (4)	

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Dec 2020 16:28:53

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Dec 2020 16:28:53

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Dec 2020 16:28:53

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE HYCLATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Feb 2021 01:40:40
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 Feb 2021 01:40:40
Data point term sent to Coder	System	08 Feb 2021 20:10:47
User entered 'Doxycycline hyclate'	(b) (4), (b) (6)	08 Feb 2021 20:10:28

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:10:28

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Right pleural effusion'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:10:28

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '110'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:10:28

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:10:28

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:10:28

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:10:28

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:10:28

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:10:28

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:10:28

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:53

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '07 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:10:28

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:10:28

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:10:28

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	08 Feb 2021 20:10:28

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:10:28

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Feb 2021 20:10:28

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Feb 2021 20:10:28

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Feb 2021 20:10:28

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:53

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Response noted. However, CM log line #3 is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 18:07:59
Query 'Per DM CLR: Response noted. However, CM log line #3 is still ongoing. ' answered with 'Line 3 I am unable to edit the end field' (Site from DM).	Kelly Woodell (b) (4)	07 Apr 2021 21:11:05
User opened query 'Per DM CLR: Response noted. However, CM log line #3 is still ongoing. ' (Site from DM).	(b) (4)	07 Apr 2021 14:13:18
User closed query "'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med 3. Review and reconcile start/stop dates so there is no overlapping. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	07 Apr 2021 14:13:18
"		
' (Site from DM).		
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
Query "'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med 3. Review and reconcile start/stop dates so there is no overlapping. Update Con Med eCRF as appropriate.	Kelly Woodell (b) (4)	26 Mar 2021 18:18:03
"	(b) (4)	
' answered with 'Stop date added to line 3		
' (Site from DM).		
User opened query "'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med 3. Review and reconcile start/stop dates so there is no overlapping. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	09 Mar 2021 13:58:58
"		
' (Site from DM).		
User coded data point as ATC:	Coder Import (b) (4)	08 Feb 2021 20:17:35
CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE BESILATE, PRODUCTSYNONYM: AMLODIPINE BESYLATE - version WHODrug-Global-B3\202003.	(b) (4)	

PRODUCTION RELEASE (v12.003
EAB) (1725)

2491 of 2654

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:53

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	08 Feb 2021 20:17:35
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	08 Feb 2021 20:16:53
User entered 'AMLODIPINE BESYLATE' reason	(b) (4), (b) (6)	08 Feb 2021 20:16:08
for change: Data Entry Error		
Data point term sent to Coder	System	08 Feb 2021 20:14:52
User entered 'Amlodipine beylate'	(b) (4), (b) (6)	08 Feb 2021 20:14:44

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:14:44

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:53

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Was this medication added because the patient experienced a worsening or exacerbation of the medical history condition being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 18:08:31
Query 'Per DM CLR: Was this medication added because the patient experienced a worsening or exacerbation of the medical history condition being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.'	(b) (4), (b) (6)	09 Apr 2021 13:44:44
answered with 'Worsening of hypertension added as an AE' (Site from DM).		
User opened query 'Per DM CLR: Was this medication added because the patient experienced a worsening or exacerbation of the medical history condition being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 14:13:43
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Hypertension'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:14:44

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '10' reason for change: Data Entry Error	Kelly Woodell (b) (4)	26 Mar 2021 18:18:11
	(b) (4)	
User entered '5'	(b) (4), (b) (6)	08 Feb 2021 20:14:44

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:14:44

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:14:44

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:14:44

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:14:44

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:14:44

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:14:44

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
User entered '15 Dec 2020' reason for change: Data Entry Error	Kelly Woodell (b) (4)	26 Mar 2021 18:20:19
	(b) (4)	
User entered '07 Feb 2021'	(b) (4), (b) (6)	08 Feb 2021 20:14:44

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:14:44

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:14:44

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:14:44

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:14:44

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Feb 2021 20:14:44

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Feb 2021 20:14:44

US3822342

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:57:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Feb 2021 20:14:44

US3822342

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:57:53

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:14:01
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:04:34
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	10 Dec 2020 16:19:48

US3822342

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:57:53

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '07 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:07:30

US3822342

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:57:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'ultrasound guided right thoracentesis'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:07:30

US3822342

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:57:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:07:30

US3822342

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:57:53

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:07:30

US3822342

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:57:53

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '05 Feb 2021'	Kelly Woodell (b) (4)	23 Feb 2021 18:57:11

US3822342

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:57:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Chest X-ray PA and Lateral'	Kelly Woodell (b) (4)	23 Feb 2021 18:57:11

US3822342

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:57:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Diagnostic (DIAGNOSTIC)'	Kelly Woodell (b) (4)	23 Feb 2021 18:57:11

US3822342

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:57:53

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:19
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	Kelly Woodell (b) (4)	23 Feb 2021 18:57:11

US3822342

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:57:53

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:30
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '05 Feb 2021'	Kelly Woodell (b) (4)	23 Feb 2021 18:57:43

US3822342

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:57:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:30
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'CT Chest with IV Contrast'	Kelly Woodell (b) (4)	23 Feb 2021 18:57:43

US3822342

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:57:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:30
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Diagnostic (DIAGNOSTIC)'	Kelly Woodell (b) (4)	23 Feb 2021 18:57:43

US3822342

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:57:53

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:30
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	Kelly Woodell (b) (4)	23 Feb 2021 18:57:43

US3822342

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:57:53

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '06 Feb 2021'	Kelly Woodell (b) (4)	23 Feb 2021 18:58:11

US3822342

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:57:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Chest X-ray'	Kelly Woodell (b) (4)	23 Feb 2021 18:58:11

US3822342

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:57:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Diagnostic (DIAGNOSTIC)'	Kelly Woodell (b) (4)	23 Feb 2021 18:58:11

US3822342

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:57:53

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	Kelly Woodell (b) (4)	23 Feb 2021 18:58:11

US3822342

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:57:53

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '22 Mar 2021'	Kelly Woodell (b) (4)	24 Mar 2021 15:16:24

US3822342

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:57:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Chest x-ray'	Kelly Woodell (b) (4)	24 Mar 2021 15:16:24

US3822342

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:57:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'Adverse Event (AE)'	Kelly Woodell (b) (4)	24 Mar 2021 15:16:24

US3822342

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:57:53

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:25:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered empty.	Kelly Woodell (b) (4)	24 Mar 2021 15:16:24

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'USA-US126-2021-MRNA-1273-P301000004'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Yes (Y)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Yes (Y)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Christina'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Kennelly'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
User closed query 'Please complete all address fields in EDC.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 16:08:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:14
Query 'Please complete all address fields in EDC.' answered with 'Completed' (Site from CRA).	Kelly Woodell (b) (4)	05 Mar 2021 15:47:30
User entered '6060 Piedmont Row Drive South'	(b) (4)	
	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22
User opened query 'Please complete all address fields in EDC.' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:30:37

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	System	25 Mar 2021 16:20:24
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:18
User entered 'Charlotte'	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	System	25 Mar 2021 16:20:24
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:20
User entered 'NC'	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	System	25 Mar 2021 16:20:24
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:22
User entered '28277'	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:51:34
User entered 'US'	System	09 Feb 2021 18:45:21

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 17:20:07
User entered '5'	System	22 Apr 2021 17:49:13
User entered '4'	System	09 Apr 2021 19:21:12
User entered '3'	System	25 Mar 2021 16:20:24
User entered '2'	System	22 Feb 2021 20:51:52
User entered '1'	System	09 Feb 2021 18:45:21

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'USA-US126-2021-MRNA-1273-P301000004'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Yes (Y)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Yes (Y)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Christina'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Kennelly'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
User closed query 'Please complete all address fields in EDC.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 16:08:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:14
Query 'Please complete all address fields in EDC.' answered with 'Completed' (Site from CRA).	Kelly Woodell (b) (4)	05 Mar 2021 15:47:30
User entered '6060 Piedmont Row Drive South'	(b) (4)	
	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22
User opened query 'Please complete all address fields in EDC.' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:30:37

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	System	25 Mar 2021 16:20:24
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:18
User entered 'Charlotte'	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	System	25 Mar 2021 16:20:24
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:20
User entered 'NC'	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	System	25 Mar 2021 16:20:24
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:22
User entered '28277'	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:51:34
User entered 'US'	System	09 Feb 2021 18:45:21

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 17:20:07
User entered '5'	System	22 Apr 2021 17:49:13
User entered '4'	System	09 Apr 2021 19:21:12
User entered '3'	System	25 Mar 2021 16:20:24
User entered '2'	System	22 Feb 2021 20:51:52
User entered '1'	System	09 Feb 2021 18:45:21

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:57:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
User entered '09/Feb/2021 12:45'	System	09 Feb 2021 18:45:21

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:57:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:51:34
User entered 'I'	(b) (4), (b) (6)	09 Feb 2021 18:45:21

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'USA-US126-2021-MRNA-1273-P301000004'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Yes (Y)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Yes (Y)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Christina'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Kennelly'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
User closed query 'Please complete all address fields in EDC.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 16:08:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:14
Query 'Please complete all address fields in EDC.' answered with 'Completed' (Site from CRA).	Kelly Woodell (b) (4)	05 Mar 2021 15:47:30
User entered '6060 Piedmont Row Drive South'	(b) (4)	
	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22
User opened query 'Please complete all address fields in EDC.' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:30:37

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	System	25 Mar 2021 16:20:24
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:18
User entered 'Charlotte'	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	System	25 Mar 2021 16:20:24
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:20
User entered 'NC'	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	System	25 Mar 2021 16:20:24
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:22
User entered '28277'	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:51:34
User entered 'US'	System	09 Feb 2021 18:45:21

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 17:20:07
User entered '5'	System	22 Apr 2021 17:49:13
User entered '4'	System	09 Apr 2021 19:21:12
User entered '3'	System	25 Mar 2021 16:20:24
User entered '2'	System	22 Feb 2021 20:51:52
User entered '1'	System	09 Feb 2021 18:45:21

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:57:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
User entered '22/Feb/2021 14:51'	System	22 Feb 2021 20:51:52

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:57:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:30:41
User entered 'I'	(b) (4), (b) (6)	22 Feb 2021 20:51:52

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'USA-US126-2021-MRNA-1273-P301000004'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Yes (Y)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Yes (Y)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Christina'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Kennelly'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
User closed query 'Please complete all address fields in EDC.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 16:08:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:14
Query 'Please complete all address fields in EDC.' answered with 'Completed' (Site from CRA).	Kelly Woodell (b) (4)	05 Mar 2021 15:47:30
User entered '6060 Piedmont Row Drive South'	(b) (4)	
	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22
User opened query 'Please complete all address fields in EDC.' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:30:37

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	System	25 Mar 2021 16:20:24
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:18
User entered 'Charlotte'	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	System	25 Mar 2021 16:20:24
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:20
User entered 'NC'	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	System	25 Mar 2021 16:20:24
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:22
User entered '28277'	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:51:34
User entered 'US'	System	09 Feb 2021 18:45:21

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 17:20:07
User entered '5'	System	22 Apr 2021 17:49:13
User entered '4'	System	09 Apr 2021 19:21:12
User entered '3'	System	25 Mar 2021 16:20:24
User entered '2'	System	22 Feb 2021 20:51:52
User entered '1'	System	09 Feb 2021 18:45:21

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:57:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered '25/Mar/2021 11:20'	(b) (4) System	25 Mar 2021 16:20:24

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:57:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
User entered 'I'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:20:24

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'USA-US126-2021-MRNA-1273-P301000004'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Yes (Y)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Yes (Y)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Christina'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Kennelly'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
User closed query 'Please complete all address fields in EDC.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 16:08:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:14
Query 'Please complete all address fields in EDC.' answered with 'Completed' (Site from CRA).	Kelly Woodell (b) (4)	05 Mar 2021 15:47:30
User entered '6060 Piedmont Row Drive South'	(b) (4)	
	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22
User opened query 'Please complete all address fields in EDC.' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:30:37

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	System	25 Mar 2021 16:20:24
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:18
User entered 'Charlotte'	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	System	25 Mar 2021 16:20:24
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:20
User entered 'NC'	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	System	25 Mar 2021 16:20:24
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:22
User entered '28277'	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:51:34
User entered 'US'	System	09 Feb 2021 18:45:21

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 17:20:07
User entered '5'	System	22 Apr 2021 17:49:13
User entered '4'	System	09 Apr 2021 19:21:12
User entered '3'	System	25 Mar 2021 16:20:24
User entered '2'	System	22 Feb 2021 20:51:52
User entered '1'	System	09 Feb 2021 18:45:21

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:57:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User entered '09/Apr/2021 15:21'	(b) (4) System	09 Apr 2021 19:21:12

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:57:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:13:27
User entered 'I'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 19:21:12

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'USA-US126-2021-MRNA-1273-P301000004'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Yes (Y)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Yes (Y)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Christina'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Kennelly'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
User closed query 'Please complete all address fields in EDC.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 16:08:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:14
Query 'Please complete all address fields in EDC.' answered with 'Completed' (Site from CRA).	Kelly Woodell (b) (4)	05 Mar 2021 15:47:30
User entered '6060 Piedmont Row Drive South'	(b) (4)	
	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22
User opened query 'Please complete all address fields in EDC.' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:30:37

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	System	25 Mar 2021 16:20:24
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:18
User entered 'Charlotte'	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	System	25 Mar 2021 16:20:24
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:20
User entered 'NC'	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	System	25 Mar 2021 16:20:24
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:22
User entered '28277'	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:51:34
User entered 'US'	System	09 Feb 2021 18:45:21

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 17:20:07
User entered '5'	System	22 Apr 2021 17:49:13
User entered '4'	System	09 Apr 2021 19:21:12
User entered '3'	System	25 Mar 2021 16:20:24
User entered '2'	System	22 Feb 2021 20:51:52
User entered '1'	System	09 Feb 2021 18:45:21

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:57:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:46:56
User entered '22/Apr/2021 10:49'	(b) (4) System	22 Apr 2021 17:49:13

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:57:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:46:56
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:49:13

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'USA-US126-2021-MRNA-1273-P301000004'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Yes (Y)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Yes (Y)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'No (N)'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Christina'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 18:45:13
User entered 'Kennelly'	System	09 Feb 2021 18:40:42

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
User closed query 'Please complete all address fields in EDC.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 16:08:16
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:14
Query 'Please complete all address fields in EDC.' answered with 'Completed' (Site from CRA).	Kelly Woodell (b) (4)	05 Mar 2021 15:47:30
User entered '6060 Piedmont Row Drive South'	(b) (4)	
	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22
User opened query 'Please complete all address fields in EDC.' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 15:30:37

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	System	25 Mar 2021 16:20:24
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:18
User entered 'Charlotte'	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	System	25 Mar 2021 16:20:24
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:20
User entered 'NC'	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:19:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
Un-reviewed for Safety.	System	25 Mar 2021 16:20:24
DataPoint Un-verified.	System	25 Mar 2021 16:20:24
User entered empty.	System	25 Mar 2021 16:20:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 16:20:06
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 16:08:22
User entered '28277'	Kelly Woodell (b) (4)	05 Mar 2021 15:47:22

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:30:41
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:51:34
User entered 'US'	System	09 Feb 2021 18:45:21

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:57:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 17:20:07
User entered '5'	System	22 Apr 2021 17:49:13
User entered '4'	System	09 Apr 2021 19:21:12
User entered '3'	System	25 Mar 2021 16:20:24
User entered '2'	System	22 Feb 2021 20:51:52
User entered '1'	System	09 Feb 2021 18:45:21

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:57:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	30 Apr 2021 20:01:40
User entered '30/Apr/2021 13:20'	(b) (4) System	30 Apr 2021 17:20:07

US3822342

Folder: SAE USA-US126-2021-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:57:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	30 Apr 2021 20:01:40
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:20:07