

US3722215 (Prod: Keystone VitaLink Research - Greenville - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:35:41

All time stamps listed in this document are displayed in GMT

US3722215

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

Participant ID

US3722215

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

US3722215

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 11:25:31

Generated On: 10 Jun 2021 09:35:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3722215

Folder: Screening

Form: Demographics

Data signed: (b) (4) 09 Mar 2021 11:25:30

Generated On: 10 Jun 2021 09:35:41

Date of Birth (MMM yyyy)	(b) (6) 1957
Age	63
Age Units	YEARS
Age (Derived)	63
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3722215

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 09 Mar 2021 11:25:30

Generated On: 10 Jun 2021 09:35:41

Date of Informed Consent (<i>dd MMM yyyy</i>)	12 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3722215

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 09 Mar 2021 11:25:30

Generated On: 10 Jun 2021 09:35:41

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3722215

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 09 Mar 2021 11:25:31

Generated On: 10 Jun 2021 09:35:41

Were any significant conditions reported?

Yes ☒

No ☐

US3722215

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

Condition	HOT FLASHES
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	

US3722215

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

Condition	HYPERCHOLESTEROLEMIA
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)	

US3722215

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

US3722215

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

Condition	IRRITABLE BOWEL SYNDROME
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)	_____

US3722215

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

US3722215

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

US3722215

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

Condition	CHRONIC BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

US3722215

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3722215

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

Condition	ENDOMETRIOSIS
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

US3722215

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

Condition	TONSILLITIS
Start date (dd MMM yyyy)	UN UNK 1963
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 1963
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1963
Start Year (derived)	1963
Stop Month and Year (derived)	JAN 1963
Stop Year (derived)	1963

US3722215

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

Condition	ANXIETY
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)	

US3722215

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

Condition	DEPRESSION
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)	_____

US3722215

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

Condition	GASTROESOPHAGEAL REFLUX DISEASE
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)	_____

US3722215

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

Condition	MIGRAINES
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)	

US3722215

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

Condition	SCOLIOSIS
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

US3722215

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 09 Mar 2021 11:25:31

Generated On: 10 Jun 2021 09:35:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 AUG 2020
Time of assessment (00:00-23:59)	14:27 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 14:27
Height (xxx.x)	62.7 in
Weight (xxx.x)	140.4 lb
BMI (xxx.x)	25.16181 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3722215

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 11:25:31

Generated On: 10 Jun 2021 09:35:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 AUG 2020

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

US3722215

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 09 Mar 2021 11:25:30

Generated On: 10 Jun 2021 09:35:41

Date of assessment (dd MMM yyyy) 12 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2003

Date of last menstruation unknown False

US3722215

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Mar 2021 11:25:31

Generated On: 10 Jun 2021 09:35:41

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3722215

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Mar 2021 11:25:31

Generated On: 10 Jun 2021 09:35:41

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)	True
Other	False
Specify	

US3722215

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

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

Visit date (dd MMM yyyy)	12 AUG 2020
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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	VISIT1
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US3722215

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

What was the date of randomization? (dd MMM yyyy) 12 AUG 2020

What was the participant's randomization number? 103467

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 ☒

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

Height	ND - Not Done
Weight	ND - Not Done

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

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)	12 AUG 2020
Time of assessment (00:00-23:59)	14:27 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 14:27
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

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)	12 AUG 2020
Time of assessment (00:00-23:59)	15:36 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 15:36
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3722215

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

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.

US3722215

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

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) 12 AUG 2020

What was the treatment time? (00:00-23:59) 15:06 (24 HR)

Treatment Date and Time (derived) 12 AUG 2020 15:06

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

US3722215

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 AUG 2020
Collection time (00:00-23:59)	14:47 (24 HR)
Collection date and time (derived)	12 AUG 2020 14:47

US3722215

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

Collection date (dd MMM yyyy)			12 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:43	12 AUG 2020 14:43
Nasopharyngeal Swab 2	Yes	14:43	12 AUG 2020 14:43

US3722215

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °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):

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

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

PC Time Stamp 12 AUG 2020 15:29

PC Open Date & Time 12 AUG 2020 15:26

PC Close Date & Time 12 AUG 2020 17:56

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

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 96.6 °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	13 AUG 2020 08:24
PC Open Date & Time	12 AUG 2020 18:51
PC Close Date & Time	13 AUG 2020 11:59

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 20:10

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:41

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

96.5 °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

14 AUG 2020 16:03

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

15 AUG 2020 17:38

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:41

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

97.1 °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

16 AUG 2020 19:40

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 22:04

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:41

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 ☒

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 19 AUG 2020 09:20

PC Open Date & Time 18 AUG 2020 12:00

PC Close Date & Time 19 AUG 2020 11:59

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

12 AUG 2020 15:26

PC Close Date & Time

12 AUG 2020 17:56

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

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

13 AUG 2020 08:25

PC Open Date & Time

12 AUG 2020 18:51

PC Close Date & Time

13 AUG 2020 11:59

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:41

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

13 AUG 2020 20:10

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:41

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

14 AUG 2020 16:03

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:41

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

15 AUG 2020 17:38

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:41

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

16 AUG 2020 19:41

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:41

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

17 AUG 2020 22:04

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:41

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

19 AUG 2020 09:20

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

12 AUG 2020 15:26

PC Close Date & Time

12 AUG 2020 17:56

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 08:25
PC Open Date & Time	12 AUG 2020 18:51
PC Close Date & Time	13 AUG 2020 11:59

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:41

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 ☒

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:41

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

59 of 2094

EAB) (1725)

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:41

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 16:03
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:41

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

61 of 2094

EAB) (1725)

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:41

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 17:39
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:41

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)

63 of 2094

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:41

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 19:42
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:41

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 ☒

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:41

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 22:04
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:41

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)

67 of 2094

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:41

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 09:20
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3722215

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722215

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722215

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3722215

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722215

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3722215

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722215

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

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 SEP 2020
Time of assessment (00:00-23:59)	13:40 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 13:40
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)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	8 SEP 2020
Time of assessment (00:00-23:59)	14:57 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 14:57
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3722215

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 SEP 2020

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

US3722215

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

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) 8 SEP 2020

What was the treatment time? (00:00-23:59) 14:27 (24 HR)

Treatment Date and Time (derived) 8 SEP 2020 14:27

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

US3722215

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 SEP 2020
Collection time (00:00-23:59)	14:08 (24 HR)
Collection date and time (derived)	8 SEP 2020 14:08

US3722215

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

Collection date (dd MMM yyyy)			8 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:03	8 SEP 2020 14:03
Nasopharyngeal Swab 2	Yes	14:03	8 SEP 2020 14:03

US3722215

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 15:00

PC Open Date & Time

08 SEP 2020 14:47

PC Close Date & Time

08 SEP 2020 17:17

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

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 98.2 °F

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

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

PC Time Stamp	08 SEP 2020 20:06
PC Open Date & Time	08 SEP 2020 18:12
PC Close Date & Time	09 SEP 2020 11:59

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

09 SEP 2020 17:45

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:41

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 21:18

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:41

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

97.8 °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

12 SEP 2020 09:36

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 07:11

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:41

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 ☒

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 08:25

PC Open Date & Time 13 SEP 2020 12:00

PC Close Date & Time 14 SEP 2020 11:59

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 09:16

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

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 SEP 2020 15:01

PC Open Date & Time

08 SEP 2020 14:47

PC Close Date & Time

08 SEP 2020 17:17

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

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 SEP 2020 20:06

PC Open Date & Time

08 SEP 2020 18:12

PC Close Date & Time

09 SEP 2020 11:59

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:41

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 SEP 2020 17:45

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:41

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 SEP 2020 21:18

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:41

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 SEP 2020 09:36

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:41

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 07:11

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:41

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 08:25

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:41

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 09:16

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 15:01
PC Open Date & Time	08 SEP 2020 14:47
PC Close Date & Time	08 SEP 2020 17:17

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 20:06
PC Open Date & Time	08 SEP 2020 18:12
PC Close Date & Time	09 SEP 2020 11:59

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

103 of 2094

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:41

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 17:46
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:41

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 ☒

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:41

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 21:19
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:41

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 ☒

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:41

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 09:37
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:41

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

109 of 2094

EAB) (1725)

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:41

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 ☒

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:41

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 08:25
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:41

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 ☒

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:41

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 09:17
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3722215

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722215

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722215

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722215

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722215

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722215

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722215

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3722215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	5 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	16:28 (24 HR)
Vital Signs Date and Time (derived)	5 OCT 2020 16:28
Temperature (<i>xxx.x</i>)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	58 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3722215

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 OCT 2020

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

US3722215

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

5 OCT 2020

Collection time (00:00-23:59)

16:36 (24 HR)

Collection date and time (derived)

5 OCT 2020 16:36

US3722215

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 14:52:32

Generated On: 10 Jun 2021 09:35:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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	15 OCT 2020 17:01:25
Patient Cloud Open Date & Time	12 OCT 2020 00:01
Patient Cloud Close Date & Time	16 OCT 2020 23:59

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

19 OCT 2020 06:43:19

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 12:00:39

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

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

Date and time of submission

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 103

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

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

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

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

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

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

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

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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="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"/>

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 <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"/>

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 DEC 2020 14:26:12

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

22 DEC 2020 09:01:17

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

27 DEC 2020 12:17:23

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 14:42:41
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 15:23:54

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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	16 JAN 2021 13:11:58
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

25 JAN 2021 18:20:58

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

30 JAN 2021 14:14:29

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 FEB 2021 08:41:46

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

12 FEB 2021 14:41:11

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 12:31:55
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 FEB 2021 21:04:22

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

06 MAR 2021 13:02:00

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

12 MAR 2021 15:33:55

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 <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	19 MAR 2021 15:47:19
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

26 MAR 2021 11:46:09

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

03 APR 2021 15:33:54

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 14:30:44

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 11:02:51

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 15:22:53

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 11:20:33

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 299

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

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

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

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

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

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

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

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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"/>

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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"/>

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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"/>

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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"/>

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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"/>

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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="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"/>

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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"/>

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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="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"/>

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 <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"/>

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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"/>

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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"/>

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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"/>

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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°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 ☐

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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"/>

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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"/>

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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"/>

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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"/>

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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°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 ☐

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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"/>

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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"/>

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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="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"/>

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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"/>

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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"/>

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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="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"/>

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3722215

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:35:41

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
Yes	No	06 MAR 2021 13:01:50

US3722215

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 17:24:19

Generated On: 10 Jun 2021 09:35:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722215

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:24:19

Generated On: 10 Jun 2021 09:35:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722215

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 4 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3722215

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722215

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722215

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722215

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722215

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722215

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 11:25:31

Generated On: 10 Jun 2021 09:35:41

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

Visit date (dd MMM yyyy)	22 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	VISIT4
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US3722215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 FEB 2021
Time of assessment (00:00-23:59)	08:36 (24 HR)
Vital Signs Date and Time (derived)	22 FEB 2021 08:36
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3722215

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 11:25:31

Generated On: 10 Jun 2021 09:35:41

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.

US3722215

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 11:25:31

Generated On: 10 Jun 2021 09:35:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 FEB 2021
Collection time (00:00-23:59)	08:37 (24 HR)
Collection date and time (derived)	22 FEB 2021 08:37

US3722215

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 11:25:31

Generated On: 10 Jun 2021 09:35:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722215

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722215

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722215

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3722215

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:35:41

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3722215

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 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

US3722215

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

Date of updated informed consent (dd MMM yyyy) 8 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 8 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3722215

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 JAN 2021

Collection time (00:00-23:59)

10:32 (24 HR)

Collection date and time (derived)

8 JAN 2021 10:32

US3722215

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 JAN 2021
Collection time (00:00 - 23:59)	10:36
Collection Date and Time (derived)	8 JAN 2021 10:36

US3722215

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

AEID	USA-US083-2021-MRNA-1273-P30 1000019
Adverse event	L3-L4 SPONDYLOLISTHESIS
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)	11 MAR 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)	14 MAR 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)	11 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	14 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

337 of 2094

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

SITE REACHED OUT TO
SUBJECT TO CONFIRM HEALTH
CHANGE. SUBJECT RETURNED
CALL ON 22 MAR 2021 AND
REPORTED AN SAE OF
WORSENING OSTEOARTHRITIS
IN HER BACK THAT WAS
LEADING TO PAIN AND
DISCOMFORT, SO SHE
UNDERWENT A LUMBAR
FUSION ON 11 MAR 2021.
SUBJECT WAS IN THE
HOSPITAL FROM 11 MAR 2021
TO 14 MAR 2021. SUBJECT
REPORTED BEING GIVEN
MULTIPLE MEDICATIONS
WHILE IN THE HOSPITAL, BUT
WAS UNABLE TO RECALL
DETAILS. SHE REPORTS ONLY
TAKING TYLENOL AT THIS
TIME. SUBJECT AGREES TO
COME TO SITE TOMORROW TO
COMPLETE A MEDICAL
RECORDS REQUEST FORM SO
ADDITIONAL DETAILS CAN BE
REPORTED. SUBJECT REPORTS
SHE IS RECOVERING VERY
WELL AT THIS TIME. PI
INFORMED OF SAE. SITE WILL
FOLLOW UP ONCE RECORDS
ARE AVAILABLE.

UPON RECEIPT OF RECORDS,
SAE WAS UPDATED WITH A
NEW TITLE AND MEDICATIONS
LISTED IN RECORDS. SITE IS
STILL PENDING THE MARS FOR
COMPLETE RECORD OF
MEDICATIONS. NO COVID
TESTING PERFORMED PER
RECORDS.

3-13-2021: HEMOGLOBIN 10.1;
HEMATOCRIT 30.0; MCV 99.7

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

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

Yes ☒

No ☐

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

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

Name of Medication COZARR

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

342 of 2094

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

	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 2013	
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"/>

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

Name of Medication CRESTOR

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEREMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

344 of 2094

EAB) (1725)

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

Name of Medication PROBIOTIC

Prophylaxis Yes ☐
No ☒

Indication IRRITABLE BOWL SYNDROME

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

346 of 2094

EAB) (1725)

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

Name of Medication CALCIUM

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

348 of 2094

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

	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"/>

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

Name of Medication FLEXERIL

Prophylaxis Yes ☐
No ☒

Indication BACK PAIN

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)

350 of 2094

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

Name of Medication GLUCOSAMINE CHONDROITIN

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 1500/1200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

352 of 2094

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

Name of Medication ESTROGEN PATCH

Prophylaxis Yes ☐
No ☒

Indication HOT FLASHES

Dose per administration 0.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY OTHER WEEK

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

PRODUCTION RELEASE (v12.003

354 of 2094

EAB) (1725)

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

	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 2004	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

Name of Medication DICLOFENAC

Prophylaxis Yes ☐
No ☒

Indication BACK PAIN

Dose per administration 100

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)

356 of 2094

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

	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 APR 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"/>

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication WORSENING OSTEOARTHRITIS
(LUMBAR)

Dose per administration 325

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)

358 of 2094

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

	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)		11 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

Name of Medication BOTOX

Prophylaxis Yes ☒
No ☐

Indication COSMETIC

Dose per administration 30

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify EVERY 3 MONTHS

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

PRODUCTION RELEASE (v12.003

360 of 2094

EAB) (1725)

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 JAN 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

Name of Medication JUVIDERM

Prophylaxis Yes ☒
No ☐

Indication COSMETIC

Dose per administration 1

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

If dose unit is Other, specify SYRINGE

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

If frequency is Other, specify EVERY 3 MONTHS

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

PRODUCTION RELEASE (v12.003

362 of 2094

EAB) (1725)

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 JAN 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication L3-L4 SPONDYLOLISTHESIS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

364 of 2094

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

	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)		13 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 13 MAR 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

Name of Medication OXYGEN

Prophylaxis Yes ☐
No ☒

Indication L2-L4 SPONDYLOLISTHESIS

Dose per administration 2

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

If dose unit is Other, specify LITERS

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

If frequency is Other, specify

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

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366 of 2094

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US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)		13 MAR 2021
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"/>

US3722215

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3722215

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Apr 2021 21:53:19

Generated On: 10 Jun 2021 09:35:41

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
11 MAR 2021	L4-L5 LUMBAR INFUSION	Medical History	

US3722215

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:35:41

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

US3722215

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:35:41

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 ☐

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

SAEID	USA-US083-2021-MRNA-1273-P301000019
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

SAEID	USA-US083-2021-MRNA-1273-P301000019
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	24/MAR/2021 06:21
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

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 21:53:20

Generated On: 10 Jun 2021 09:35:41

SAEID	USA-US083-2021-MRNA-1273-P301000019
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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	21/APR/2021 10:54
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3722215 (Prod: Keystone VitaLink Research - Greenville - PPDS)

US3722215

Form: Participant Creation

Generated On: 10 Jun 2021 09:35:41

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'US3722215'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 18:14:33

US3722215

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:35:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	12 Aug 2020 19:08:41

US3722215

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '12 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 18:14:34

US3722215

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'Clinic (Clinic)'	Taylor Wilson (b) (4)	12 Aug 2020 19:08:41

US3722215

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:35:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'SCRN'	System	12 Aug 2020 19:08:41

US3722215

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:41

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered (b) (6) 1957'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 18:14:35

US3722215

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:41

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '63'	Taylor Wilson (b) (4)	12 Aug 2020 19:08:53

US3722215

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:41

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'YEARS'	System	12 Aug 2020 19:08:53

US3722215

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:41

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '63'	System	12 Aug 2020 19:09:32

US3722215

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:41

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
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	12 Aug 2020 19:09:04
User entered 'Female (F)' reason for change: Data Entry Error	Taylor Wilson (b) (4)	12 Aug 2020 19:09:04
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	12 Aug 2020 19:08:53
	Taylor Wilson (b) (4)	12 Aug 2020 19:08:53
	(b) (4)	

US3722215

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:41

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
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	12 Aug 2020 19:09:04
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' reason for change: Data Entry Error	Taylor Wilson (b) (4)	12 Aug 2020 19:09:04
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	12 Aug 2020 19:08:53
	Taylor Wilson (b) (4)	12 Aug 2020 19:08:53
	(b) (4)	

US3722215

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:41

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User closed query 'Race has not been provided. Please correct.' (Site from System).	(b) (4)	
User entered '1' reason for change: Data Entry Error	System	12 Aug 2020 19:09:04
User opened query 'Race has not been provided. Please correct.' (Site from System).	Taylor Wilson (b) (4)	12 Aug 2020 19:09:04
User entered '0'	(b) (4)	
	System	12 Aug 2020 19:08:53
	Taylor Wilson (b) (4)	12 Aug 2020 19:08:53
	(b) (4)	

US3722215

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:41

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Taylor Wilson (b) (4)	12 Aug 2020 19:08:53

US3722215

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:41

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Taylor Wilson (b) (4)	12 Aug 2020 19:08:53

US3722215

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:41

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Taylor Wilson (b) (4)	12 Aug 2020 19:08:53

US3722215

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:41

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Taylor Wilson (b) (4)	12 Aug 2020 19:08:53

US3722215

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:41

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Taylor Wilson (b) (4)	12 Aug 2020 19:08:53

US3722215

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:41

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered empty.	(b) (4) Taylor Wilson (b) (4)	12 Aug 2020 19:08:53

US3722215

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:41

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Taylor Wilson (b) (4)	12 Aug 2020 19:08:53

US3722215

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:35:41

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Taylor Wilson (b) (4)	12 Aug 2020 19:08:53

US3722215

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:35:41

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '12 Aug 2020'	Taylor Wilson (b) (4)	12 Aug 2020 19:09:32

US3722215

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'Aug 2020'	System	12 Aug 2020 19:09:32

US3722215

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '2020'	System	12 Aug 2020 19:09:32

US3722215

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:35:41

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User closed query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:20:46
Query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' answered with 'completed' (Site from DM).	Kayla Peay (b) (4) (b) (4)	17 Sep 2020 15:11:47
User entered 'Amendment 2 (2)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	17 Sep 2020 15:11:44
User opened query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 04:56:00
User entered 'Amendment 5 (5)'	Taylor Wilson (b) (4) (b) (4)	12 Aug 2020 19:09:32

US3722215

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	12 Aug 2020 19:09:32

US3722215

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:35:41

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered empty.	(b) (4) Taylor Wilson (b) (4)	12 Aug 2020 19:09:32

US3722215

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:35:41

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered empty.	(b) (4) Taylor Wilson (b) (4)	12 Aug 2020 19:09:32

US3722215

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:35:41

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'No (N)'	Taylor Wilson (b) (4)	12 Aug 2020 19:09:32

US3722215

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:35:41

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 18:14:34

US3722215

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:35:41

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'I'	System	12 Aug 2020 19:09:39

US3722215

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	12 Aug 2020 19:09:39

US3722215

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:35:41

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'Yes (Y)'	Kayla Peay (b) (4)	13 Aug 2020 15:01:30

US3722215

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:35:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User coded data point as SOC: Vascular disorders, HLT: Vascular disorders NEC, HLT: Peripheral vascular disorders NEC, PT: Hot flush, LLT: Hot flashes - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 15:03:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 15:03:29
Data point term sent to Coder	System	13 Aug 2020 15:02:24
User entered 'hot flashes'	Kayla Peay (b) (4)	13 Aug 2020 15:01:44

US3722215

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'un UNK 2003'	Kayla Peay (b) (4)	13 Aug 2020 15:01:44

US3722215

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:35:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Kayla Peay (b) (4)	13 Aug 2020 15:01:44

US3722215

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:35:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'Yes (Y)'	Kayla Peay (b) (4)	13 Aug 2020 15:01:44

US3722215

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered empty.	Kayla Peay (b) (4)	13 Aug 2020 15:01:44

US3722215

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:35:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Kayla Peay (b) (4)	13 Aug 2020 15:01:44

US3722215

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'Jan 2003'	System	13 Aug 2020 15:01:44

US3722215

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '2003'	System	13 Aug 2020 15:01:44

US3722215

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	System	13 Aug 2020 15:01:44

US3722215

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	System	13 Aug 2020 15:01:44

US3722215

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:35:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	13 Aug 2020 15:03:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 15:03:29
Data point term sent to Coder	System	13 Aug 2020 15:02:26
User entered 'hypercholesterolemia'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:02:05

US3722215

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'un UNK 2005'	Kayla Peay (b) (4)	13 Aug 2020 15:02:05

US3722215

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:35:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Kayla Peay (b) (4)	13 Aug 2020 15:02:05

US3722215

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:35:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'Yes (Y)'	Kayla Peay (b) (4)	13 Aug 2020 15:02:05

US3722215

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered empty.	Kayla Peay (b) (4)	13 Aug 2020 15:02:05

US3722215

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:35:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Kayla Peay (b) (4)	13 Aug 2020 15:02:05

US3722215

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'Jan 2005'	System	13 Aug 2020 15:02:05

US3722215

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '2005'	System	13 Aug 2020 15:02:05

US3722215

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	System	13 Aug 2020 15:02:05

US3722215

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	System	13 Aug 2020 15:02:05

US3722215

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:35:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User coded data point as SOC: Vascular disorders, HLTG: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 15:03:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 15:03:29
Data point term sent to Coder	System	13 Aug 2020 15:02:27
User entered 'hypertension'	Kayla Peay (b) (4)	13 Aug 2020 15:02:21
	(b) (4)	

US3722215

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'un UNK 2013'	Kayla Peay (b) (4)	13 Aug 2020 15:02:21

US3722215

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:35:41

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Kayla Peay (b) (4)	13 Aug 2020 15:02:21

US3722215

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:35:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'Yes (Y)'	Kayla Peay (b) (4)	13 Aug 2020 15:02:21

US3722215

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered empty.	Kayla Peay (b) (4)	13 Aug 2020 15:02:21

US3722215

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:35:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Kayla Peay (b) (4)	13 Aug 2020 15:02:21

US3722215

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'Jan 2013'	System	13 Aug 2020 15:02:21

US3722215

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '2013'	System	13 Aug 2020 15:02:21

US3722215

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	System	13 Aug 2020 15:02:21

US3722215

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	System	13 Aug 2020 15:02:21

US3722215

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:35:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User closed query 'Per MM, please expand the abbreviation ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:27:57
User coded data point as SOC: Gastrointestinal disorders, HLGt: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Irritable bowel syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 15:37:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 15:37:47
Query 'Per MM, please expand the abbreviation ' answered with 'UPDATED' (Site from DM).	Amy Ford (b) (4) (b) (4)	21 Sep 2020 15:36:45
Data point term sent to Coder	System	21 Sep 2020 15:36:41
Coding entries removed.	Amy Ford (b) (4) (b) (4)	21 Sep 2020 15:36:40
User entered 'IRRITABLE BOWEL SYNDROME' reason for change: Per Query Resolution	Amy Ford (b) (4) (b) (4)	21 Sep 2020 15:36:40
User opened query 'Per MM, please expand the abbreviation ' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 21:04:40
User coded data point as SOC: Gastrointestinal disorders, HLGt: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Irritable bowel syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 15:04:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 15:04:22
Data point term sent to Coder	System	13 Aug 2020 15:03:30
User entered 'IBS'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:02:33

US3722215

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'un UNK 2010'	Kayla Peay (b) (4)	13 Aug 2020 15:02:33

US3722215

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:35:41

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Kayla Peay (b) (4)	13 Aug 2020 15:02:33

US3722215

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:35:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'Yes (Y)'	Kayla Peay (b) (4)	13 Aug 2020 15:02:33

US3722215

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered empty.	Kayla Peay (b) (4)	13 Aug 2020 15:02:33

US3722215

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:35:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Kayla Peay (b) (4)	13 Aug 2020 15:02:33

US3722215

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'Jan 2010'	System	13 Aug 2020 15:02:33

US3722215

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '2010'	System	13 Aug 2020 15:02:33

US3722215

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	System	13 Aug 2020 15:02:33

US3722215

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	System	13 Aug 2020 15:02:33

US3722215

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:35:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 15:04:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 15:04:47
Data point term sent to Coder	System	13 Aug 2020 15:03:30
User entered 'insomnia'	Kayla Peay (b) (4)	13 Aug 2020 15:02:48

US3722215

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'un UNK 2008'	Kayla Peay (b) (4)	13 Aug 2020 15:02:48

US3722215

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:35:41

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Kayla Peay (b) (4)	13 Aug 2020 15:02:48

US3722215

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:35:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'Yes (Y)'	Kayla Peay (b) (4)	13 Aug 2020 15:02:48

US3722215

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered empty.	Kayla Peay (b) (4)	13 Aug 2020 15:02:48

US3722215

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:35:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Kayla Peay (b) (4)	13 Aug 2020 15:02:48

US3722215

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'Jan 2008'	System	13 Aug 2020 15:02:48

US3722215

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '2008'	System	13 Aug 2020 15:02:48

US3722215

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	System	13 Aug 2020 15:02:48

US3722215

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	System	13 Aug 2020 15:02:48

US3722215

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:35:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 15:04:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 15:04:22
Data point term sent to Coder	System	13 Aug 2020 15:03:32
User entered 'osteoarthritis'	Kayla Peay (b) (4)	13 Aug 2020 15:03:02

US3722215

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'un UNK 2008'	Kayla Peay (b) (4)	13 Aug 2020 15:03:02

US3722215

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:35:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Kayla Peay (b) (4)	13 Aug 2020 15:03:02

US3722215

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:35:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'Yes (Y)'	Kayla Peay (b) (4)	13 Aug 2020 15:03:02

US3722215

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered empty.	Kayla Peay (b) (4)	13 Aug 2020 15:03:02

US3722215

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:35:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Kayla Peay (b) (4)	13 Aug 2020 15:03:02

US3722215

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'Jan 2008'	System	13 Aug 2020 15:03:02

US3722215

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '2008'	System	13 Aug 2020 15:03:02

US3722215

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	System	13 Aug 2020 15:03:02

US3722215

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	System	13 Aug 2020 15:03:02

US3722215

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:35:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User closed query 'Per MM, please review and update the term to final diagnosis ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 07:37:20
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 18:20:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 18:20:44
Query 'Per MM, please review and update the term to final diagnosis ' answered with 'Updated per request ' (Site from DM).	Sara Poff (b) (4) (b) (4)	21 Oct 2020 18:19:35
Data point term sent to Coder	System	21 Oct 2020 18:19:29
Coding entries removed.	Sara Poff (b) (4) (b) (4)	21 Oct 2020 18:19:18
User entered 'Chronic BACK PAIN' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	21 Oct 2020 18:19:18
User opened query 'Per MM, please review and update the term to final diagnosis ' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 21:04:19
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 15:06:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 15:06:38
Data point term sent to Coder	System	13 Aug 2020 15:05:40
User entered 'back pain'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:05:13

US3722215

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'un UNK 2008'	Kayla Peay (b) (4)	13 Aug 2020 15:05:13

US3722215

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:35:41

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Kayla Peay (b) (4)	13 Aug 2020 15:05:13

US3722215

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:35:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'Yes (Y)'	Kayla Peay (b) (4)	13 Aug 2020 15:05:13

US3722215

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered empty.	Kayla Peay (b) (4)	13 Aug 2020 15:05:13

US3722215

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:35:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Kayla Peay (b) (4)	13 Aug 2020 15:05:13

US3722215

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'Jan 2008'	System	13 Aug 2020 15:05:13

US3722215

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '2008'	System	13 Aug 2020 15:05:13

US3722215

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	System	13 Aug 2020 15:05:13

US3722215

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	System	13 Aug 2020 15:05:13

US3722215

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:35:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 15:06:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 15:06:38
Data point term sent to Coder	System	13 Aug 2020 15:05:39
User entered 'post menopausal'	Kayla Peay (b) (4)	13 Aug 2020 15:05:26

US3722215

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'un UNK 2003'	Kayla Peay (b) (4)	13 Aug 2020 15:05:26

US3722215

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:35:41

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Kayla Peay (b) (4)	13 Aug 2020 15:05:26

US3722215

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:35:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'Yes (Y)'	Kayla Peay (b) (4)	13 Aug 2020 15:05:26

US3722215

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered empty.	Kayla Peay (b) (4)	13 Aug 2020 15:05:26

US3722215

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:35:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Kayla Peay (b) (4)	13 Aug 2020 15:05:26

US3722215

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'Jan 2003'	System	13 Aug 2020 15:05:26

US3722215

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '2003'	System	13 Aug 2020 15:05:26

US3722215

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	System	13 Aug 2020 15:05:26

US3722215

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	System	13 Aug 2020 15:05:26

US3722215

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:35:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 15:07:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 15:07:18
Data point term sent to Coder	System	13 Aug 2020 15:06:41
User entered 'endometriosis'	Kayla Peay (b) (4)	13 Aug 2020 15:05:47

US3722215

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'un UNK 1995'	Kayla Peay (b) (4)	13 Aug 2020 15:05:47

US3722215

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:35:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Kayla Peay (b) (4)	13 Aug 2020 15:05:47

US3722215

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:35:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'No (N)'	Kayla Peay (b) (4)	13 Aug 2020 15:05:47

US3722215

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'un UNK 1995'	Kayla Peay (b) (4)	13 Aug 2020 15:05:47

US3722215

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:35:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Kayla Peay (b) (4)	13 Aug 2020 15:05:47

US3722215

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'Jan 1995'	System	13 Aug 2020 15:05:47

US3722215

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '1995'	System	13 Aug 2020 15:05:47

US3722215

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'Jan 1995'	System	13 Aug 2020 15:05:47

US3722215

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '1995'	System	13 Aug 2020 15:05:47

US3722215

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:35:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	13 Aug 2020 15:07:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 15:07:17
Data point term sent to Coder	System	13 Aug 2020 15:06:44
User entered 'tonsillitis'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:06:07

US3722215

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'un UNK 1963'	Kayla Peay (b) (4)	13 Aug 2020 15:06:07

US3722215

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:35:41

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Kayla Peay (b) (4)	13 Aug 2020 15:06:07

US3722215

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:35:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'No (N)'	Kayla Peay (b) (4)	13 Aug 2020 15:06:07

US3722215

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'un UNK 1963'	Kayla Peay (b) (4)	13 Aug 2020 15:06:07

US3722215

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:35:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Kayla Peay (b) (4)	13 Aug 2020 15:06:07

US3722215

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'Jan 1963'	System	13 Aug 2020 15:06:07

US3722215

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '1963'	System	13 Aug 2020 15:06:07

US3722215

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'Jan 1963'	System	13 Aug 2020 15:06:07

US3722215

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '1963'	System	13 Aug 2020 15:06:07

US3722215

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:35:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 04:02:26
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 16:50:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 16:50:40
Data point term sent to Coder	System	20 Apr 2021 16:49:56
User entered 'Anxiety'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 16:49:34

US3722215

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'un UNK 2010'	Marlee Smith (b) (4)	20 Apr 2021 16:49:34

US3722215

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:35:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '0'	Marlee Smith (b) (4)	20 Apr 2021 16:49:34

US3722215

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:35:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'Yes (Y)'	Marlee Smith (b) (4)	20 Apr 2021 16:49:34

US3722215

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	Marlee Smith (b) (4)	20 Apr 2021 16:49:34

US3722215

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:35:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '0'	Marlee Smith (b) (4)	20 Apr 2021 16:49:34

US3722215

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'Jan 2010'	System	20 Apr 2021 16:49:34

US3722215

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '2010'	System	20 Apr 2021 16:49:34

US3722215

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	System	20 Apr 2021 16:49:34

US3722215

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	System	20 Apr 2021 16:49:34

US3722215

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:35:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 04:02:26
User coded data point as SOC: Psychiatric disorders, HLT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 16:50:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 16:50:38
Data point term sent to Coder	System	20 Apr 2021 16:49:57
User entered 'depression'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 16:49:49

US3722215

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'un UNK 2010'	Marlee Smith (b) (4)	20 Apr 2021 16:49:49

US3722215

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:35:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '0'	Marlee Smith (b) (4)	20 Apr 2021 16:49:49

US3722215

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:35:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 16:49:49

US3722215

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	Marlee Smith (b) (4)	20 Apr 2021 16:49:49

US3722215

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:35:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '0'	Marlee Smith (b) (4)	20 Apr 2021 16:49:49

US3722215

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'Jan 2010'	System	20 Apr 2021 16:49:49

US3722215

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '2010'	System	20 Apr 2021 16:49:49

US3722215

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	System	20 Apr 2021 16:49:49

US3722215

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	System	20 Apr 2021 16:49:49

US3722215

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:35:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 04:02:26
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 16:51:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 16:51:39
Data point term sent to Coder	System	20 Apr 2021 16:51:00
User entered 'gastroesophageal reflux disease'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 16:50:14

US3722215

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'un UNK 2010'	Marlee Smith (b) (4)	20 Apr 2021 16:50:14

US3722215

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:35:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '0'	Marlee Smith (b) (4)	20 Apr 2021 16:50:14

US3722215

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:35:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'Yes (Y)'	Marlee Smith (b) (4)	20 Apr 2021 16:50:14

US3722215

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	Marlee Smith (b) (4)	20 Apr 2021 16:50:14

US3722215

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:35:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '0'	Marlee Smith (b) (4)	20 Apr 2021 16:50:14

US3722215

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'Jan 2010'	System	20 Apr 2021 16:50:14

US3722215

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '2010'	System	20 Apr 2021 16:50:14

US3722215

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	System	20 Apr 2021 16:50:14

US3722215

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	System	20 Apr 2021 16:50:14

US3722215

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:35:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 04:02:26
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 16:51:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 16:51:38
Data point term sent to Coder	System	20 Apr 2021 16:51:00
User entered 'Migraines'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 16:50:26

US3722215

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'un UNK 2010'	Marlee Smith (b) (4)	20 Apr 2021 16:50:26

US3722215

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:35:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '0'	Marlee Smith (b) (4)	20 Apr 2021 16:50:26

US3722215

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:35:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'Yes (Y)'	Marlee Smith (b) (4)	20 Apr 2021 16:50:26

US3722215

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	Marlee Smith (b) (4)	20 Apr 2021 16:50:26

US3722215

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:35:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '0'	Marlee Smith (b) (4)	20 Apr 2021 16:50:26

US3722215

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'Jan 2010'	System	20 Apr 2021 16:50:26

US3722215

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '2010'	System	20 Apr 2021 16:50:26

US3722215

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	System	20 Apr 2021 16:50:26

US3722215

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	System	20 Apr 2021 16:50:26

US3722215

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:35:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 04:02:26
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Scoliosis, LLT: Scoliosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 16:51:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 16:51:39
Data point term sent to Coder	System	20 Apr 2021 16:51:00
User entered 'scoliosis'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 16:50:40

US3722215

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'un UNK 2000'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 16:50:40

US3722215

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:35:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '0'	Marlee Smith (b) (4)	20 Apr 2021 16:50:40

US3722215

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:35:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'Yes (Y)'	Marlee Smith (b) (4)	20 Apr 2021 16:50:40

US3722215

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	Marlee Smith (b) (4)	20 Apr 2021 16:50:40

US3722215

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:35:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '0'	Marlee Smith (b) (4)	20 Apr 2021 16:50:40

US3722215

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered 'Jan 2000'	System	20 Apr 2021 16:50:40

US3722215

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered '2000'	System	20 Apr 2021 16:50:40

US3722215

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	System	20 Apr 2021 16:50:40

US3722215

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:27:34
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:07:12
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User entered empty.	System	20 Apr 2021 16:50:40

US3722215

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'Yes (Y)'	Kayla Peay (b) (4)	13 Aug 2020 15:07:14

US3722215

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '12 Aug 2020'	Kayla Peay (b) (4)	13 Aug 2020 15:07:14

US3722215

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '14:27'	Kayla Peay (b) (4)	13 Aug 2020 15:07:14

US3722215

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User entered '12 Aug 2020 14:27'	System	13 Aug 2020 15:07:14

US3722215

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '62.7' in	(b) (4) Kayla Peay (b) (4)	13 Aug 2020 15:07:14
DataPoint set to visible.	(b) (4) System	12 Aug 2020 19:09:39

US3722215

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '140.4' lb	(b) (4) Kayla Peay (b) (4)	13 Aug 2020 15:07:14
DataPoint set to visible.	(b) (4) System	12 Aug 2020 19:09:39

US3722215

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
Amendment Manager: User entered '25.16181'	System	16 Sep 2020 23:54:02
User entered '25.2'	System	13 Aug 2020 15:07:14
DataPoint set to visible.	System	12 Aug 2020 19:09:39

US3722215

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User entered 'kg/m2'	System	13 Aug 2020 15:07:14
DataPoint set to visible.	System	12 Aug 2020 19:09:39

US3722215

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 18:46:20
User entered '98.7' F	Kayla Peay (b) (4)	13 Aug 2020 15:07:14
	(b) (4)	

US3722215

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered empty; reason for change Data Entry Error	(b) (4)	
	Kayla Peay (b) (4)	08 Sep 2020 18:46:20
User entered 'Oral (Oral)'	(b) (4)	
	Kayla Peay (b) (4)	13 Aug 2020 15:07:14
	(b) (4)	

US3722215

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered empty.	(b) (4) Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:07:14

US3722215

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 18:46:20
User entered '73'	Kayla Peay (b) (4)	13 Aug 2020 15:07:14
	(b) (4)	

US3722215

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User entered 'bpm'	System	13 Aug 2020 15:07:14

US3722215

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 18:46:20
User entered '17'	Kayla Peay (b) (4)	13 Aug 2020 15:07:14
	(b) (4)	

US3722215

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User entered 'breaths/min'	System	13 Aug 2020 15:07:14

US3722215

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 18:46:20
User entered '118'	Kayla Peay (b) (4)	13 Aug 2020 15:07:14
	(b) (4)	

US3722215

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User entered 'mmHg'	System	13 Aug 2020 15:07:14

US3722215

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 18:46:20
User entered '80'	Kayla Peay (b) (4)	13 Aug 2020 15:07:14
	(b) (4)	

US3722215

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User entered 'mmHg'	System	13 Aug 2020 15:07:14

US3722215

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36

US3722215

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36

US3722215

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:35:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'Yes (Y)'	Kayla Peay (b) (4)	13 Aug 2020 15:07:18

US3722215

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:35:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 08:59:18
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 18:48:30
User entered '12 Aug 2020'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:07:18

US3722215

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:35:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '12 Aug 2020'	(b) (4) Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:07:31

US3722215

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:35:41

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'No (N)'	Kayla Peay (b) (4)	13 Aug 2020 15:07:31

US3722215

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:35:41

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Kayla Peay (b) (4)	13 Aug 2020 15:07:31

US3722215

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:35:41

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered empty.	Kayla Peay (b) (4)	13 Aug 2020 15:07:31

US3722215

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered empty.	(b) (4) Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:07:31

US3722215

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:35:41

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Kayla Peay (b) (4)	13 Aug 2020 15:07:31

US3722215

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:35:41

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'un UNK 2003'	Kayla Peay (b) (4)	13 Aug 2020 15:07:31

US3722215

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:35:41

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Kayla Peay (b) (4)	13 Aug 2020 15:07:31

US3722215

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:41

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'No (N)'	(b) (4) Taylor Wilson (b) (4)	12 Aug 2020 19:10:58

US3722215

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:41

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'No (N)'	(b) (4) Taylor Wilson (b) (4)	12 Aug 2020 19:10:58

US3722215

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:41

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	12 Aug 2020 19:10:58

US3722215

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:41

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'No (N)'	Taylor Wilson (b) (4)	12 Aug 2020 19:10:58

US3722215

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:41

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'No (N)'	Taylor Wilson (b) (4)	12 Aug 2020 19:10:58

US3722215

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:41

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'No (N)'	Taylor Wilson (b) (4)	12 Aug 2020 19:10:58

US3722215

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:41

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'No (N)'	Taylor Wilson (b) (4)	12 Aug 2020 19:10:58

US3722215

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:41

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'No (N)'	Taylor Wilson (b) (4)	12 Aug 2020 19:10:58

US3722215

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:41

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'No (N)'	(b) (4) Taylor Wilson (b) (4)	12 Aug 2020 19:10:58

US3722215

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:41

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'No (N)'	Taylor Wilson (b) (4)	12 Aug 2020 19:10:58

US3722215

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:41

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'No (N)'	Taylor Wilson (b) (4)	12 Aug 2020 19:10:58

US3722215

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:41

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'No (N)'	Taylor Wilson (b) (4)	12 Aug 2020 19:10:58

US3722215

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:41

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered empty.	(b) (4) Taylor Wilson (b) (4)	12 Aug 2020 19:10:58

US3722215

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:41

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Taylor Wilson (b) (4)	12 Aug 2020 19:10:58

US3722215

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:41

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Taylor Wilson (b) (4)	12 Aug 2020 19:10:58

US3722215

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Taylor Wilson (b) (4)	12 Aug 2020 19:10:58

US3722215

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:41

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	(b) (4) Taylor Wilson (b) (4)	12 Aug 2020 19:10:58

US3722215

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:41

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Taylor Wilson (b) (4)	12 Aug 2020 19:10:58

US3722215

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:41

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'I'	(b) (4) Taylor Wilson (b) (4)	12 Aug 2020 19:10:58

US3722215

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:41

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '0'	Taylor Wilson (b) (4)	12 Aug 2020 19:10:58

US3722215

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:35:41

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:26
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered empty.	(b) (4) Taylor Wilson (b) (4)	12 Aug 2020 19:10:58

US3722215

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:35:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	12 Aug 2020 19:11:35

US3722215

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '12 Aug 2020'	Taylor Wilson (b) (4)	12 Aug 2020 19:11:35

US3722215

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Clinic (Clinic)'	Taylor Wilson (b) (4)	12 Aug 2020 19:11:35

US3722215

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:35:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User entered 'VISIT1'	System	12 Aug 2020 19:11:35

US3722215

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '12 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 18:49:21

US3722215

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:35:41

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:57:11
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:57:11
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 18:49:21
User entered '103467' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 18:49:21

US3722215

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:35:41

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 18:49:21

US3722215

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:35:41

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)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'No (N)'	Taylor Wilson (b) (4)	12 Aug 2020 19:11:54

US3722215

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:35:41

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)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'No (N)'	Taylor Wilson (b) (4)	12 Aug 2020 19:11:54

US3722215

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:35:41

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'No (N)'	Taylor Wilson (b) (4)	12 Aug 2020 19:11:54

US3722215

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:35:41

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'No (N)'	Taylor Wilson (b) (4)	12 Aug 2020 19:11:54

US3722215

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:35:41

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'No (N)'	Taylor Wilson (b) (4)	12 Aug 2020 19:11:54

US3722215

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:35:41

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User closed query 'per CDM: please input yes or no in this field' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:47:18
Query 'per CDM: please input yes or no in this field' answered with 'updated' (Site from DM).	Marlee Smith (b) (4)	21 Dec 2020 20:33:53
User entered 'No (N)'	(b) (4) Marlee Smith (b) (4)	21 Dec 2020 20:33:49
User opened query 'per CDM: please input yes or no in this field' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:42:36
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:18:54
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:50:37

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:35:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 18:46:31
User entered '62.7' in	Kayla Peay (b) (4)	13 Aug 2020 15:08:57
	(b) (4)	

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:35:41

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 18:46:31
User entered '140.4' lb	Kayla Peay (b) (4)	13 Aug 2020 15:08:57
	(b) (4)	

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:35:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 18:46:31
User entered '62.7' in	Kayla Peay (b) (4)	13 Aug 2020 15:08:57
	(b) (4)	

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:35:41

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 18:46:31
User entered '140.4' lb	Kayla Peay (b) (4)	13 Aug 2020 15:08:57
	(b) (4)	

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User accepted default value 'Pre-Dose (PREDOSE)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Kayla Peay (b) (4)	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '12 Aug 2020'	Kayla Peay (b) (4)	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '14:27'	Kayla Peay (b) (4)	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User entered '12 Aug 2020 14:27'	System	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '98.7' F	Kayla Peay (b) (4)	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered empty.	Kayla Peay (b) (4)	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '73'	Kayla Peay (b) (4)	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User entered 'bpm'	System	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '17'	Kayla Peay (b) (4)	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User entered 'breaths/min'	System	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '118'	Kayla Peay (b) (4)	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User entered 'mmHg'	System	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '80'	Kayla Peay (b) (4)	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User entered 'mmHg'	System	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:35:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 18:46:31
User entered '62.7' in	Kayla Peay (b) (4)	13 Aug 2020 15:08:57
	(b) (4)	

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:35:41

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 18:46:31
User entered '140.4' lb	Kayla Peay (b) (4)	13 Aug 2020 15:08:57
	(b) (4)	

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User accepted default value 'Post-Dose (POSTDOSE)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Kayla Peay (b) (4)	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '12 Aug 2020'	Kayla Peay (b) (4)	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	18 Aug 2020 06:56:30
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		13 Aug 2020 15:08:57
User entered '15:36'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User entered '12 Aug 2020 15:36'	System	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '98.3' F	Kayla Peay (b) (4)	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered empty.	Kayla Peay (b) (4)	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '74'	Kayla Peay (b) (4)	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User entered 'bpm'	System	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '18'	Kayla Peay (b) (4)	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User entered 'breaths/min'	System	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '121'	Kayla Peay (b) (4)	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User entered 'mmHg'	System	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '77'	Kayla Peay (b) (4)	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User entered 'mmHg'	System	13 Aug 2020 15:08:57

US3722215

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:35:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	08 Sep 2020 18:46:39
User entered 'Yes (Y)'	Kayla Peay (b) (4)	13 Aug 2020 15:09:05
	(b) (4)	

US3722215

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:35:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 18:46:39
User entered '12 Aug 2020'	Kayla Peay (b) (4)	13 Aug 2020 15:09:05

US3722215

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:35:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	12 Aug 2020 19:12:24

US3722215

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:35:41

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered empty.	Taylor Wilson (b) (4)	12 Aug 2020 19:12:24

US3722215

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:35:41

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)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered empty.	Taylor Wilson (b) (4)	12 Aug 2020 19:12:24

US3722215

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:35:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User entered 'MRNA-1273 OR PLACEBO'	System	12 Aug 2020 19:12:24

US3722215

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:35:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '12 Aug 2020'	Taylor Wilson (b) (4)	12 Aug 2020 19:12:24

US3722215

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:35:41

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '15:06'	Taylor Wilson (b) (4)	12 Aug 2020 19:12:24

US3722215

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:35:41

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User entered '12 Aug 2020 15:06'	System	12 Aug 2020 19:12:24

US3722215

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:35:41

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Left Arm (LEFT ARM)'	Taylor Wilson (b) (4)	12 Aug 2020 19:12:24

US3722215

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:35:41

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User entered 'ONCE'	System	12 Aug 2020 19:12:24

US3722215

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:35:41

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User entered 'INTRAMUSCULAR'	System	12 Aug 2020 19:12:24

US3722215

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Kayla Peay (b) (4)	13 Aug 2020 15:09:16

US3722215

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:41

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '12 Aug 2020'	Kayla Peay (b) (4)	13 Aug 2020 15:09:16

US3722215

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '14:47'	Kayla Peay (b) (4)	13 Aug 2020 15:09:16

US3722215

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User entered '12 Aug 2020 14:47'	System	13 Aug 2020 15:09:16

US3722215

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:35:41

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '12 Aug 2020'	Kayla Peay (b) (4)	13 Aug 2020 15:09:28

US3722215

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:35:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:09:28

US3722215

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:35:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Kayla Peay (b) (4)	13 Aug 2020 15:09:28

US3722215

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:35:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '14:43'	Kayla Peay (b) (4)	13 Aug 2020 15:09:28

US3722215

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:35:41

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User entered '12 Aug 2020 14:43'	System	13 Aug 2020 15:09:28

US3722215

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:35:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:09:28

US3722215

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:35:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Kayla Peay (b) (4)	13 Aug 2020 15:09:28

US3722215

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:35:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '14:43'	Kayla Peay (b) (4)	13 Aug 2020 15:09:28

US3722215

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:35:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User entered '12 Aug 2020 14:43'	System	13 Aug 2020 15:09:28

US3722215

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Kayla Peay (b) (4)	13 Aug 2020 14:56:38

US3722215

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User entered 'I'	System	13 Aug 2020 14:56:38

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-12T15:28:48', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'd12a5774-43a2-4173-9419-7fd996761c54' User entered 'Yes (Y)'	System	12 Aug 2020 19:29:20
	System	12 Aug 2020 19:29:20

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-12T15:28:55', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'd12a5774-43a2-4173-9419-7fd996761c54' User entered '98.3'	System	12 Aug 2020 19:29:20
	System	12 Aug 2020 19:29:20

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-12T15:29:02', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'd12a5774-43a2-4173-9419-7fd996761c54'	System	12 Aug 2020 19:29:20
User entered 'Yes (Y)'	System	12 Aug 2020 19:29:20

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User closed query 'Please consider capturing the concomitant medication taken to treat pain or fever as a medication with a corresponding indication has not been captured.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 14:04:55
Query 'Please consider capturing the concomitant medication taken to treat pain or fever as a medication with a corresponding indication has not been captured.' answered with 'no conmed changes reported' (Site from CRA).	Amy Ford (b) (4) (b) (4)	21 Oct 2020 00:58:25
User opened query 'Please consider capturing the concomitant medication taken to treat pain or fever as a medication with a corresponding indication has not been captured.' (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 19:05:30
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 13:13:22
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Amy Ford (b) (4) (b) (4)	17 Aug 2020 17:11:49
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	12 Aug 2020 19:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-12T15:29:10', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'd12a5774-43a2-4173-9419-7fd996761c54'	System	12 Aug 2020 19:29:20
User entered '1'	System	12 Aug 2020 19:29:20

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-12T15:29:10', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'd12a5774-43a2-4173-9419-7fd996761c54' User entered '0'	System	12 Aug 2020 19:29:20
	System	12 Aug 2020 19:29:20

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-12T15:29:18', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'd12a5774-43a2-4173-9419-7fd996761c54'	System	12 Aug 2020 19:29:20
User entered '12 Aug 2020 15:29'	System	12 Aug 2020 19:29:20

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '12 Aug 2020 15:26'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '12 Aug 2020 17:56'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T08:24:11', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '8584dd3c-0be0-4e51-a58c-f7c1f39a0f78' User entered 'Yes (Y)'	System	13 Aug 2020 12:24:34
	System	13 Aug 2020 12:24:34

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T08:24:20', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '8584dd3c-0be0-4e51-a58c-f7c1f39a0f78' User entered '96.6'	System	13 Aug 2020 12:24:34
	System	13 Aug 2020 12:24:34

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T08:24:25', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '8584dd3c-0be0-4e51-a58c-f7c1f39a0f78'	System	13 Aug 2020 12:24:34
User entered 'No (N)'	System	13 Aug 2020 12:24:34

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T08:24:32', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '8584dd3c-0be0-4e51-a58c-f7c1f39a0f78'	System	13 Aug 2020 12:24:34
User entered '13 Aug 2020 08:24'	System	13 Aug 2020 12:24:34

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '12 Aug 2020 18:51'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 2'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T20:09:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'e5bb421a-9059-43ad-88c7-a432fa8c3676' User entered 'Yes (Y)'	System	14 Aug 2020 00:10:26
	System	14 Aug 2020 00:10:26

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T20:10:12', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'e5bb421a-9059-43ad-88c7-a432fa8c3676' User entered '97.0'	System	14 Aug 2020 00:10:26
	System	14 Aug 2020 00:10:26

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T20:10:18', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'e5bb421a-9059-43ad-88c7-a432fa8c3676'	System	14 Aug 2020 00:10:26
User entered 'No (N)'	System	14 Aug 2020 00:10:26

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T20:10:24', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'e5bb421a-9059-43ad-88c7-a432fa8c3676'	System	14 Aug 2020 00:10:26
User entered '13 Aug 2020 20:10'	System	14 Aug 2020 00:10:26

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 3'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-14T16:02:50', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'c6094ea6-914a-4d1a-84ba-1275c6d81993' User entered 'Yes (Y)'	System	14 Aug 2020 20:03:10
	System	14 Aug 2020 20:03:10

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-14T16:02:57', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'c6094ea6-914a-4d1a-84ba-1275c6d81993' User entered '96.5'	System	14 Aug 2020 20:03:10
	System	14 Aug 2020 20:03:10

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-14T16:03:01', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'c6094ea6-914a-4d1a-84ba-1275c6d81993'	System	14 Aug 2020 20:03:10
User entered 'No (N)'	System	14 Aug 2020 20:03:10

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-14T16:03:06', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'c6094ea6-914a-4d1a-84ba-1275c6d81993'	System	14 Aug 2020 20:03:10
User entered '14 Aug 2020 16:03'	System	14 Aug 2020 20:03:10

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 4'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-15T17:38:09', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '9bc5b707-35ff-4877-a31d-3c731c789b1d' User entered 'Yes (Y)'	System	15 Aug 2020 21:38:27
	System	15 Aug 2020 21:38:27

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-15T17:38:14', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '9bc5b707-35ff-4877-a31d-3c731c789b1d' User entered '98.5'	System	15 Aug 2020 21:38:27
	System	15 Aug 2020 21:38:27

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-15T17:38:19', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '9bc5b707-35ff-4877-a31d-3c731c789b1d' User entered 'No (N)'	System	15 Aug 2020 21:38:27
	System	15 Aug 2020 21:38:27

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-15T17:38:22', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '9bc5b707-35ff-4877-a31d-3c731c789b1d' User entered '15 Aug 2020 17:38'	System	15 Aug 2020 21:38:27
	System	15 Aug 2020 21:38:27

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 5'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-16T19:40:27', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'a112389e-c5a6-428c-8610-03143b2050b9' User entered 'Yes (Y)'	System	16 Aug 2020 23:40:59
	System	16 Aug 2020 23:40:59

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-16T19:40:49', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'a112389e-c5a6-428c-8610-03143b2050b9' User entered '97.1'	System	16 Aug 2020 23:40:59
	System	16 Aug 2020 23:40:59

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-16T19:40:53', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'a112389e-c5a6-428c-8610-03143b2050b9' User entered 'No (N)'	System	16 Aug 2020 23:40:59
	System	16 Aug 2020 23:40:59

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-16T19:40:57', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'a112389e-c5a6-428c-8610-03143b2050b9' User entered '16 Aug 2020 19:40'	System	16 Aug 2020 23:40:59
	System	16 Aug 2020 23:40:59

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 6'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-17T22:03:54', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'ce1ec753-36a6-4299-b153-953b7f28ad2b' User entered 'Yes (Y)'	System	18 Aug 2020 02:04:15
	System	18 Aug 2020 02:04:15

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-17T22:04:02', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'ce1ec753-36a6-4299-b153-953b7f28ad2b' User entered '98.0'	System	18 Aug 2020 02:04:15
	System	18 Aug 2020 02:04:15

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-17T22:04:06', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'ce1ec753-36a6-4299-b153-953b7f28ad2b' User entered 'No (N)'	System	18 Aug 2020 02:04:15
	System	18 Aug 2020 02:04:15

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-17T22:04:09', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'ce1ec753-36a6-4299-b153-953b7f28ad2b' User entered '17 Aug 2020 22:04'	System	18 Aug 2020 02:04:15
	System	18 Aug 2020 02:04:15

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 7'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-19T09:20:20', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '2cf9d8f5-9e49-45ac-8c96-83e0c45e7122'	System	19 Aug 2020 13:20:28
User entered 'No (N)'	System	19 Aug 2020 13:20:28

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-19T09:20:23', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '2cf9d8f5-9e49-45ac-8c96-83e0c45e7122'	System	19 Aug 2020 13:20:28
User entered 'No (N)'	System	19 Aug 2020 13:20:28

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-19T09:20:26', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '2cf9d8f5-9e49-45ac-8c96-83e0c45e7122'	System	19 Aug 2020 13:20:28
User entered '19 Aug 2020 09:20'	System	19 Aug 2020 13:20:28

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

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)	05 Mar 2021 02:04:05

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

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)	05 Mar 2021 02:04:05

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '12 Aug 2020 15:26'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '12 Aug 2020 17:56'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T08:24:41', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'c5ec6000-3fc5-445c-a4f7-b5400fba781d'	System	13 Aug 2020 12:25:10
User entered 'None (1)'	System	13 Aug 2020 12:25:10

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T08:24:47', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'c5ec6000-3fc5-445c-a4f7-b5400fba781d'	System	13 Aug 2020 12:25:10
User entered 'No (N)'	System	13 Aug 2020 12:25:10

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T08:24:55', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'c5ec6000-3fc5-445c-a4f7-b5400fba781d'	System	13 Aug 2020 12:25:10
User entered 'No (N)'	System	13 Aug 2020 12:25:10

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T08:25:02', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'c5ec6000-3fc5-445c-a4f7-b5400fba781d'	System	13 Aug 2020 12:25:10
User entered 'None (1)'	System	13 Aug 2020 12:25:10

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T08:25:08', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'c5ec6000-3fc5-445c-a4f7-b5400fba781d' User entered '13 Aug 2020 08:25'	System	13 Aug 2020 12:25:10
	System	13 Aug 2020 12:25:10

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '12 Aug 2020 18:51'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 2'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T20:10:37', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '89923368-6426-4944-aec2-2038fa43acd6'	System	14 Aug 2020 00:10:59
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 00:10:59

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T20:10:41', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '89923368-6426-4944-aec2-2038fa43acd6'	System	14 Aug 2020 00:10:59
User entered 'No (N)'	System	14 Aug 2020 00:10:59

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T20:10:46', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '89923368-6426-4944-aec2-2038fa43acd6'	System	14 Aug 2020 00:10:59
User entered 'No (N)'	System	14 Aug 2020 00:10:59

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T20:10:54', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '89923368-6426-4944-aec2-2038fa43acd6'	System	14 Aug 2020 00:10:59
User entered 'None (1)'	System	14 Aug 2020 00:10:59

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T20:10:57', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '89923368-6426-4944-aec2-2038fa43acd6'	System	14 Aug 2020 00:10:59
User entered '13 Aug 2020 20:10'	System	14 Aug 2020 00:10:59

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 3'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-14T16:03:12', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '94445546-faba-46f7-b4ad-5d1ac8556af9'	System	14 Aug 2020 20:03:28
User entered 'None (1)'	System	14 Aug 2020 20:03:28

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-14T16:03:14', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '94445546-faba-46f7-b4ad-5d1ac8556af9' User entered 'No (N)'	System	14 Aug 2020 20:03:28
	System	14 Aug 2020 20:03:28

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-14T16:03:17', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '94445546-faba-46f7-b4ad-5d1ac8556af9' User entered 'No (N)'	System	14 Aug 2020 20:03:28
	System	14 Aug 2020 20:03:28

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-14T16:03:20', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '94445546-faba-46f7-b4ad-5d1ac8556af9' User entered 'None (1)'	System	14 Aug 2020 20:03:28
	System	14 Aug 2020 20:03:28

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-14T16:03:24', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '94445546-faba-46f7-b4ad-5d1ac8556af9' User entered '14 Aug 2020 16:03'	System	14 Aug 2020 20:03:28
	System	14 Aug 2020 20:03:28

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 4'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-15T17:38:28', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'b6bc25ee-4404-4de9-a4dc-77a0cd548c73'	System	15 Aug 2020 21:38:40
User entered 'None (1)'	System	15 Aug 2020 21:38:40

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-15T17:38:30', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'b6bc25ee-4404-4de9-a4dc-77a0cd548c73'	System	15 Aug 2020 21:38:40
User entered 'No (N)'	System	15 Aug 2020 21:38:40

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-15T17:38:33', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'b6bc25ee-4404-4de9-a4dc-77a0cd548c73'	System	15 Aug 2020 21:38:40
User entered 'No (N)'	System	15 Aug 2020 21:38:40

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-15T17:38:35', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'b6bc25ee-4404-4de9-a4dc-77a0cd548c73'	System	15 Aug 2020 21:38:40
User entered 'None (1)'	System	15 Aug 2020 21:38:40

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-15T17:38:39', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'b6bc25ee-4404-4de9-a4dc-77a0cd548c73' User entered '15 Aug 2020 17:38'	System	15 Aug 2020 21:38:40
	System	15 Aug 2020 21:38:40

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 5'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-16T19:41:19', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '6c36d47c-e75b-4e50-b5ac-7ea196c8b241' User entered 'None (1)'	System	16 Aug 2020 23:41:53
	System	16 Aug 2020 23:41:53

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-16T19:41:22', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '6c36d47c-e75b-4e50-b5ac-7ea196c8b241' User entered 'No (N)'	System	16 Aug 2020 23:41:53
	System	16 Aug 2020 23:41:53

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-16T19:41:27', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '6c36d47c-e75b-4e50-b5ac-7ea196c8b241' User entered 'No (N)'	System	16 Aug 2020 23:41:53
	System	16 Aug 2020 23:41:53

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-16T19:41:45', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '6c36d47c-e75b-4e50-b5ac-7ea196c8b241' User entered 'None (1)'	System	16 Aug 2020 23:41:53
	System	16 Aug 2020 23:41:53

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-16T19:41:49', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '6c36d47c-e75b-4e50-b5ac-7ea196c8b241' User entered '16 Aug 2020 19:41'	System	16 Aug 2020 23:41:53
	System	16 Aug 2020 23:41:53

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 6'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-17T22:04:15', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '34db8acc-1eee-4705-a235-2edcdf6d5a46'	System	18 Aug 2020 02:04:28
User entered 'None (1)'	System	18 Aug 2020 02:04:28

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-17T22:04:18', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '34db8acc-1eee-4705-a235-2edcdf6d5a46'	System	18 Aug 2020 02:04:28
User entered 'No (N)'	System	18 Aug 2020 02:04:28

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-17T22:04:20', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '34db8acc-1eee-4705-a235-2edcdf6d5a46'	System	18 Aug 2020 02:04:28
User entered 'No (N)'	System	18 Aug 2020 02:04:28

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-17T22:04:23', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '34db8acc-1eee-4705-a235-2edcdf6d5a46'	System	18 Aug 2020 02:04:28
User entered 'None (1)'	System	18 Aug 2020 02:04:28

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-17T22:04:26', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '34db8acc-1eee-4705-a235-2edcdf6d5a46'	System	18 Aug 2020 02:04:28
User entered '17 Aug 2020 22:04'	System	18 Aug 2020 02:04:28

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 7'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-19T09:20:30', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '9098f578-c26b-4f8f-bed7-477f80c5053d'	System	19 Aug 2020 13:20:42
User entered 'None (1)'	System	19 Aug 2020 13:20:42

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-19T09:20:32', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '9098f578-c26b-4f8f-bed7-477f80c5053d'	System	19 Aug 2020 13:20:42
User entered 'No (N)'	System	19 Aug 2020 13:20:42

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-19T09:20:35', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '9098f578-c26b-4f8f-bed7-477f80c5053d' User entered 'No (N)'	System	19 Aug 2020 13:20:42
	System	19 Aug 2020 13:20:42

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-19T09:20:37', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '9098f578-c26b-4f8f-bed7-477f80c5053d'	System	19 Aug 2020 13:20:42
User entered 'None (1)'	System	19 Aug 2020 13:20:42

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-19T09:20:40', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '9098f578-c26b-4f8f-bed7-477f80c5053d'	System	19 Aug 2020 13:20:42
User entered '19 Aug 2020 09:20'	System	19 Aug 2020 13:20:42

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

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)	05 Mar 2021 02:04:05

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '12 Aug 2020 15:26'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '12 Aug 2020 17:56'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T08:25:16', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '93e5919a-2475-4a58-b326-50644e37b7a4' User entered 'None (0)'	System	13 Aug 2020 12:25:46
	System	13 Aug 2020 12:25:46

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T08:25:20', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '93e5919a-2475-4a58-b326-50644e37b7a4' User entered 'None (0)'	System	13 Aug 2020 12:25:46
	System	13 Aug 2020 12:25:46

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T08:25:23', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '93e5919a-2475-4a58-b326-50644e37b7a4' User entered 'None (0)'	System	13 Aug 2020 12:25:46
	System	13 Aug 2020 12:25:46

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T08:25:27', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '93e5919a-2475-4a58-b326-50644e37b7a4' User entered 'None (0)'	System	13 Aug 2020 12:25:46
	System	13 Aug 2020 12:25:46

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T08:25:29', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '93e5919a-2475-4a58-b326-50644e37b7a4' User entered 'None (0)'	System	13 Aug 2020 12:25:46
	System	13 Aug 2020 12:25:46

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T08:25:32', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '93e5919a-2475-4a58-b326-50644e37b7a4' User entered 'None (0)'	System	13 Aug 2020 12:25:46
	System	13 Aug 2020 12:25:46

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

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)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T08:25:36', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '93e5919a-2475-4a58-b326-50644e37b7a4'	System	13 Aug 2020 12:25:46
User entered 'No (N)'	System	13 Aug 2020 12:25:46

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T08:25:41', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '93e5919a-2475-4a58-b326-50644e37b7a4' User entered '13 Aug 2020 08:25'	System	13 Aug 2020 12:25:46
	System	13 Aug 2020 12:25:46

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '12 Aug 2020 18:51'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 2'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T20:11:03', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'c6fcd4f1-f627-4a18-8d62-6bb54e1b6e9b' User entered 'None (0)'	System	14 Aug 2020 00:11:23
	System	14 Aug 2020 00:11:23

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T20:11:06', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'c6fcd4f1-f627-4a18-8d62-6bb54e1b6e9b' User entered 'None (0)'	System	14 Aug 2020 00:11:23
	System	14 Aug 2020 00:11:23

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T20:11:09', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'c6fcd4f1-f627-4a18-8d62-6bb54e1b6e9b' User entered 'None (0)'	System	14 Aug 2020 00:11:23
	System	14 Aug 2020 00:11:23

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T20:11:11', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'c6fcd4f1-f627-4a18-8d62-6bb54e1b6e9b' User entered 'None (0)'	System	14 Aug 2020 00:11:23
	System	14 Aug 2020 00:11:23

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T20:11:13', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'c6fcd4f1-f627-4a18-8d62-6bb54e1b6e9b' User entered 'None (0)'	System	14 Aug 2020 00:11:23
	System	14 Aug 2020 00:11:23

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T20:11:15', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'c6fcd4f1-f627-4a18-8d62-6bb54e1b6e9b' User entered 'None (0)'	System	14 Aug 2020 00:11:23
	System	14 Aug 2020 00:11:23

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:41

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)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T20:11:19', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'c6fcd4f1-f627-4a18-8d62-6bb54e1b6e9b'	System	14 Aug 2020 00:11:23
User entered 'No (N)'	System	14 Aug 2020 00:11:23

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-13T20:11:22', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'c6fcd4f1-f627-4a18-8d62-6bb54e1b6e9b' User entered '13 Aug 2020 20:11'	System	14 Aug 2020 00:11:23
	System	14 Aug 2020 00:11:23

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 3'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-14T16:03:31', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '12e2a3a0-4d23-4d59-88e7-5a1ed47208c3' User entered 'None (0)'	System	14 Aug 2020 20:03:56
	System	14 Aug 2020 20:03:56

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-14T16:03:36', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '12e2a3a0-4d23-4d59-88e7-5a1ed47208c3' User entered 'None (0)'	System	14 Aug 2020 20:03:56
	System	14 Aug 2020 20:03:56

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-14T16:03:40', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '12e2a3a0-4d23-4d59-88e7-5a1ed47208c3' User entered 'None (0)'	System	14 Aug 2020 20:03:56
	System	14 Aug 2020 20:03:56

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-14T16:03:43', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '12e2a3a0-4d23-4d59-88e7-5a1ed47208c3' User entered 'None (0)'	System	14 Aug 2020 20:03:56
	System	14 Aug 2020 20:03:56

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-14T16:03:45', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '12e2a3a0-4d23-4d59-88e7-5a1ed47208c3' User entered 'None (0)'	System	14 Aug 2020 20:03:56
	System	14 Aug 2020 20:03:56

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-14T16:03:47', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '12e2a3a0-4d23-4d59-88e7-5a1ed47208c3' User entered 'None (0)'	System	14 Aug 2020 20:03:56
	System	14 Aug 2020 20:03:56

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:41

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)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-14T16:03:50', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '12e2a3a0-4d23-4d59-88e7-5a1ed47208c3' User entered 'No (N)'	System	14 Aug 2020 20:03:56
	System	14 Aug 2020 20:03:56

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-14T16:03:54', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '12e2a3a0-4d23-4d59-88e7-5a1ed47208c3' User entered '14 Aug 2020 16:03'	System	14 Aug 2020 20:03:56
	System	14 Aug 2020 20:03:56

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 4'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-15T17:38:43', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '0e3d65d4-e5c3-4a41-9411-f66eaba5c102' User entered 'None (0)'	System	15 Aug 2020 21:39:04
	System	15 Aug 2020 21:39:04

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-15T17:38:45', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '0e3d65d4-e5c3-4a41-9411-f66eaba5c102' User entered 'None (0)'	System	15 Aug 2020 21:39:04
	System	15 Aug 2020 21:39:04

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-15T17:38:48', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '0e3d65d4-e5c3-4a41-9411-f66eaba5c102' User entered 'None (0)'	System	15 Aug 2020 21:39:04
	System	15 Aug 2020 21:39:04

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-15T17:38:51', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '0e3d65d4-e5c3-4a41-9411-f66eaba5c102' User entered 'None (0)'	System	15 Aug 2020 21:39:04
	System	15 Aug 2020 21:39:04

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-15T17:38:53', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '0e3d65d4-e5c3-4a41-9411-f66eaba5c102' User entered 'None (0)'	System	15 Aug 2020 21:39:04
	System	15 Aug 2020 21:39:04

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-15T17:38:55', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '0e3d65d4-e5c3-4a41-9411-f66eaba5c102' User entered 'None (0)'	System	15 Aug 2020 21:39:04
	System	15 Aug 2020 21:39:04

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:41

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)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-15T17:38:59', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '0e3d65d4-e5c3-4a41-9411-f66eaba5c102'	System	15 Aug 2020 21:39:04
User entered 'No (N)'	System	15 Aug 2020 21:39:04

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-15T17:39:01', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '0e3d65d4-e5c3-4a41-9411-f66eaba5c102'	System	15 Aug 2020 21:39:04
User entered '15 Aug 2020 17:39'	System	15 Aug 2020 21:39:04

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 5'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-16T19:41:58', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '64b7e492-b86b-42ed-8e40-3dd2f1251366' User entered 'None (0)'	System	16 Aug 2020 23:42:58
	System	16 Aug 2020 23:42:58

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-16T19:42:04', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '64b7e492-b86b-42ed-8e40-3dd2f1251366' User entered 'None (0)'	System	16 Aug 2020 23:42:58
	System	16 Aug 2020 23:42:58

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-16T19:42:07', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '64b7e492-b86b-42ed-8e40-3dd2f1251366' User entered 'None (0)'	System	16 Aug 2020 23:42:58
	System	16 Aug 2020 23:42:58

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-16T19:42:12', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '64b7e492-b86b-42ed-8e40-3dd2f1251366' User entered 'None (0)'	System	16 Aug 2020 23:42:58
	System	16 Aug 2020 23:42:58

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-16T19:42:18', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '64b7e492-b86b-42ed-8e40-3dd2f1251366' User entered 'None (0)'	System	16 Aug 2020 23:42:58
	System	16 Aug 2020 23:42:58

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-16T19:42:20', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '64b7e492-b86b-42ed-8e40-3dd2f1251366' User entered 'None (0)'	System	16 Aug 2020 23:42:58
	System	16 Aug 2020 23:42:58

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:41

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)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-16T19:42:33', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '64b7e492-b86b-42ed-8e40-3dd2f1251366' User entered 'No (N)'	System	16 Aug 2020 23:42:58
	System	16 Aug 2020 23:42:58

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-16T19:42:54', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '64b7e492-b86b-42ed-8e40-3dd2f1251366' User entered '16 Aug 2020 19:42'	System	16 Aug 2020 23:42:58
	System	16 Aug 2020 23:42:58

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 6'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-17T22:04:32', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'a95318b3-efeb-4d29-b911-fbfba616e1e4' User entered 'None (0)'	System	18 Aug 2020 02:04:53
	System	18 Aug 2020 02:04:53

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-17T22:04:35', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'a95318b3-efeb-4d29-b911-fbfba616e1e4' User entered 'None (0)'	System	18 Aug 2020 02:04:53
	System	18 Aug 2020 02:04:53

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-17T22:04:37', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'a95318b3-efeb-4d29-b911-fbfba616e1e4' User entered 'None (0)'	System	18 Aug 2020 02:04:53
	System	18 Aug 2020 02:04:53

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-17T22:04:39', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'a95318b3-efeb-4d29-b911-fbfba616e1e4' User entered 'None (0)'	System	18 Aug 2020 02:04:53
	System	18 Aug 2020 02:04:53

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-17T22:04:41', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'a95318b3-efeb-4d29-b911-fbfba616e1e4' User entered 'None (0)'	System	18 Aug 2020 02:04:53
	System	18 Aug 2020 02:04:53

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-17T22:04:43', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'a95318b3-efeb-4d29-b911-fbfba616e1e4' User entered 'None (0)'	System	18 Aug 2020 02:04:53
	System	18 Aug 2020 02:04:53

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:41

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)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-17T22:04:46', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'a95318b3-efeb-4d29-b911-fbfba616e1e4' User entered 'No (N)'	System	18 Aug 2020 02:04:53
	System	18 Aug 2020 02:04:53

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-17T22:04:49', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'a95318b3-efeb-4d29-b911-fbfba616e1e4' User entered '17 Aug 2020 22:04'	System	18 Aug 2020 02:04:53
	System	18 Aug 2020 02:04:53

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 7'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-19T09:20:44', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '5cc5749d-3a2b-4dcc-a9f6-882cb4210dfe' User entered 'None (0)'	System	19 Aug 2020 13:21:02
	System	19 Aug 2020 13:21:02

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-19T09:20:45', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '5cc5749d-3a2b-4dcc-a9f6-882cb4210dfe' User entered 'None (0)'	System	19 Aug 2020 13:21:02
	System	19 Aug 2020 13:21:02

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-19T09:20:47', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '5cc5749d-3a2b-4dcc-a9f6-882cb4210dfe' User entered 'None (0)'	System	19 Aug 2020 13:21:02
	System	19 Aug 2020 13:21:02

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-19T09:20:49', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '5cc5749d-3a2b-4dcc-a9f6-882cb4210dfe' User entered 'None (0)'	System	19 Aug 2020 13:21:02
	System	19 Aug 2020 13:21:02

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-19T09:20:51', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '5cc5749d-3a2b-4dcc-a9f6-882cb4210dfe' User entered 'None (0)'	System	19 Aug 2020 13:21:02
	System	19 Aug 2020 13:21:02

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-19T09:20:52', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '5cc5749d-3a2b-4dcc-a9f6-882cb4210dfe' User entered 'None (0)'	System	19 Aug 2020 13:21:02
	System	19 Aug 2020 13:21:02

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:41

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)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-19T09:20:57', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '5cc5749d-3a2b-4dcc-a9f6-882cb4210dfe' User entered 'No (N)'	System	19 Aug 2020 13:21:02
	System	19 Aug 2020 13:21:02

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-08-19T09:20:59', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '5cc5749d-3a2b-4dcc-a9f6-882cb4210dfe' User entered '19 Aug 2020 09:20'	System	19 Aug 2020 13:21:02
	System	19 Aug 2020 13:21:02

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 19:12:24

US3722215

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 19:12:24

US3722215

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Amy Ford (b) (4)	23 Aug 2020 01:00:36

US3722215

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '22 Aug 2020'	Amy Ford (b) (4)	23 Aug 2020 01:00:36

US3722215

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Contact Made (CONTACT MADE)'	Amy Ford (b) (4)	23 Aug 2020 01:00:36

US3722215

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered empty.	Amy Ford (b) (4)	23 Aug 2020 01:00:36

US3722215

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Amy Ford (b) (4)	23 Aug 2020 01:00:41

US3722215

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User entered 'I'	System	23 Aug 2020 01:00:41

US3722215

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Kayla Peay (b) (4)	31 Aug 2020 13:53:05

US3722215

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '28 Aug 2020'	Kayla Peay (b) (4)	31 Aug 2020 13:53:05

US3722215

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	31 Aug 2020 13:53:05

US3722215

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered empty.	Kayla Peay (b) (4)	31 Aug 2020 13:53:05

US3722215

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Kayla Peay (b) (4)	31 Aug 2020 13:53:08

US3722215

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User entered 'I'	System	31 Aug 2020 13:53:08

US3722215

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Kayla Peay (b) (4)	08 Sep 2020 18:04:22

US3722215

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '2 Sep 2020'	Kayla Peay (b) (4)	08 Sep 2020 18:04:22

US3722215

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	08 Sep 2020 18:04:22

US3722215

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered empty.	Kayla Peay (b) (4)	08 Sep 2020 18:04:22

US3722215

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Kayla Peay (b) (4)	08 Sep 2020 18:04:24

US3722215

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User entered 'I'	System	08 Sep 2020 18:04:24

US3722215

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Sara Poff (b) (4)	08 Sep 2020 18:48:30

US3722215

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:41

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User closed query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:38:21
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Per protocol subject is in window per -3 day window ' (Site from System).	Sara Poff (b) (4) (b) (4)	08 Sep 2020 18:49:13
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	08 Sep 2020 18:48:30
User entered '8 Sep 2020'	Sara Poff (b) (4) (b) (4)	08 Sep 2020 18:48:30

US3722215

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Clinic (Clinic)'	Sara Poff (b) (4)	08 Sep 2020 18:48:30

US3722215

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User entered 'VISIT2'	System	08 Sep 2020 18:48:30

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User accepted default value 'Pre-Dose (PREDOSE)'	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Kayla Peay (b) (4)	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '8 Sep 2020'	Kayla Peay (b) (4)	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '13:40'	Kayla Peay (b) (4)	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User entered '8 Sep 2020 13:40'	System	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '97.7' F	Kayla Peay (b) (4)	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered empty.	Kayla Peay (b) (4)	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '66'	Kayla Peay (b) (4)	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User entered 'bpm'	System	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '18'	Kayla Peay (b) (4)	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User entered 'breaths/min'	System	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '135'	Kayla Peay (b) (4)	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User entered 'mmHg'	System	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '86'	Kayla Peay (b) (4)	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:35:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User entered 'mmHg'	System	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User accepted default value 'Post-Dose (POSTDOSE)'	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Kayla Peay (b) (4)	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '8 Sep 2020'	Kayla Peay (b) (4)	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 19:16:20
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 19:16:20
User entered '14:57' reason for change: Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 19:16:20
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 18:05:12
User entered empty.	Kayla Peay (b) (4)	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User entered '8 Sep 2020 14:57'	System	08 Sep 2020 19:16:20
User entered empty.	System	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 19:16:20
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 19:16:20
User entered '98.2' F reason for change: Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 19:16:20
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 18:05:12
User entered empty.	Kayla Peay (b) (4)	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered empty.	Kayla Peay (b) (4)	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	08 Sep 2020 19:16:20
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 19:16:20
User entered '66' reason for change: Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 19:16:20
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	08 Sep 2020 18:05:12
User entered empty.	Kayla Peay (b) (4)	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User entered 'bpm'	System	08 Sep 2020 19:16:20
User entered empty.	System	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	08 Sep 2020 19:16:20
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 19:16:20
User entered '18' reason for change: Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 19:16:20
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	08 Sep 2020 18:05:12
User entered empty.	Kayla Peay (b) (4)	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User entered 'breaths/min'	System	08 Sep 2020 19:16:20
User entered empty.	System	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	08 Sep 2020 19:16:20
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 19:16:20
User entered '130' reason for change: Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 19:16:20
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	08 Sep 2020 18:05:12
User entered empty.	Kayla Peay (b) (4)	08 Sep 2020 18:05:12
	(b) (4)	

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User entered 'mmHg'	System	08 Sep 2020 19:16:20
User entered empty.	System	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	08 Sep 2020 19:16:20
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 19:16:20
User entered '88' reason for change: Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 19:16:20
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	08 Sep 2020 18:05:12
User entered empty.	Kayla Peay (b) (4)	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:35:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User entered 'mmHg'	System	08 Sep 2020 19:16:20
User entered empty.	System	08 Sep 2020 18:05:12

US3722215

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:35:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Kayla Peay (b) (4)	08 Sep 2020 18:05:22

US3722215

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:35:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '8 Sep 2020'	Kayla Peay (b) (4)	08 Sep 2020 18:05:22

US3722215

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Sara Poff (b) (4)	08 Sep 2020 18:52:55

US3722215

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:41

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered empty.	Sara Poff (b) (4)	08 Sep 2020 18:52:55

US3722215

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:41

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)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered empty.	Sara Poff (b) (4)	08 Sep 2020 18:52:55

US3722215

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 18:52:55

US3722215

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '8 Sep 2020'	Sara Poff (b) (4)	08 Sep 2020 18:52:55

US3722215

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:41

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '14:27'	Sara Poff (b) (4)	08 Sep 2020 18:52:55

US3722215

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:41

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User entered '8 Sep 2020 14:27'	System	08 Sep 2020 18:52:55

US3722215

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:41

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Left Arm (LEFT ARM)'	Sara Poff (b) (4)	08 Sep 2020 18:52:55

US3722215

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:41

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User entered 'ONCE'	System	08 Sep 2020 18:52:55

US3722215

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:35:41

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 18:52:55

US3722215

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Kayla Peay (b) (4)	08 Sep 2020 19:15:07

US3722215

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:41

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '8 Sep 2020'	Kayla Peay (b) (4)	08 Sep 2020 19:15:07

US3722215

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '14:08'	Kayla Peay (b) (4)	08 Sep 2020 19:15:07

US3722215

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User entered '8 Sep 2020 14:08'	System	08 Sep 2020 19:15:07

US3722215

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:35:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '8 Sep 2020'	Kayla Peay (b) (4)	08 Sep 2020 19:15:22

US3722215

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:35:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 19:15:22

US3722215

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:35:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Kayla Peay (b) (4)	08 Sep 2020 19:15:22

US3722215

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:35:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '14:03'	Kayla Peay (b) (4)	08 Sep 2020 19:15:22

US3722215

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:35:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User entered '8 Sep 2020 14:03'	System	08 Sep 2020 19:15:22

US3722215

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:35:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 19:15:22

US3722215

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:35:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Kayla Peay (b) (4)	08 Sep 2020 19:15:22

US3722215

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:35:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '14:03'	Kayla Peay (b) (4)	08 Sep 2020 19:15:22

US3722215

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:35:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User entered '8 Sep 2020 14:03'	System	08 Sep 2020 19:15:22

US3722215

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Sara Poff (b) (4)	08 Sep 2020 18:54:20

US3722215

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User entered '1'	System	08 Sep 2020 18:54:20

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	08 Sep 2020 18:52:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T15:00:43', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'f4b2fa9d-1b17-45f8-ac18-a6706f8d5bde' User entered 'Yes (Y)'	System	08 Sep 2020 19:01:01
	System	08 Sep 2020 19:01:01

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T15:00:49', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'f4b2fa9d-1b17-45f8-ac18-a6706f8d5bde' User entered '98.2'	System	08 Sep 2020 19:01:01
	System	08 Sep 2020 19:01:01

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T15:00:53', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'f4b2fa9d-1b17-45f8-ac18-a6706f8d5bde'	System	08 Sep 2020 19:01:01
User entered 'No (N)'	System	08 Sep 2020 19:01:01

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T15:00:56', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'f4b2fa9d-1b17-45f8-ac18-a6706f8d5bde' User entered '08 Sep 2020 15:00'	System	08 Sep 2020 19:01:01
	System	08 Sep 2020 19:01:01

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '08 Sep 2020 14:47'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '08 Sep 2020 17:17'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	08 Sep 2020 18:52:55
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T20:05:56', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '5f214f91-2936-48b6-881b-774e3e05b56d' User entered 'Yes (Y)'	System	09 Sep 2020 00:06:20
	System	09 Sep 2020 00:06:20

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T20:06:04', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '5f214f91-2936-48b6-881b-774e3e05b56d' User entered '98.2'	System	09 Sep 2020 00:06:20
	System	09 Sep 2020 00:06:20

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T20:06:08', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '5f214f91-2936-48b6-881b-774e3e05b56d' User entered 'No (N)'	System	09 Sep 2020 00:06:20
	System	09 Sep 2020 00:06:20

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T20:06:15', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '5f214f91-2936-48b6-881b-774e3e05b56d' User entered '08 Sep 2020 20:06'	System	09 Sep 2020 00:06:20
	System	09 Sep 2020 00:06:20

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '08 Sep 2020 18:12'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	08 Sep 2020 18:52:55
User entered 'Day 2'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-09T17:45:19', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'e01a28a5-48cf-4d99-aa95-0f077bcd767d' User entered 'Yes (Y)'	System	09 Sep 2020 21:45:34
	System	09 Sep 2020 21:45:34

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-09T17:45:25', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'e01a28a5-48cf-4d99-aa95-0f077bcd767d' User entered '98.4'	System	09 Sep 2020 21:45:34
	System	09 Sep 2020 21:45:34

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-09T17:45:29', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'e01a28a5-48cf-4d99-aa95-0f077bcd767d' User entered 'No (N)'	System	09 Sep 2020 21:45:34
	System	09 Sep 2020 21:45:34

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-09T17:45:32', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'e01a28a5-48cf-4d99-aa95-0f077bcd767d' User entered '09 Sep 2020 17:45'	System	09 Sep 2020 21:45:34
	System	09 Sep 2020 21:45:34

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	08 Sep 2020 18:52:55
User entered 'Day 3'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-10T21:18:20', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '8bed3312-035b-431e-8ee7-1482a596f548'	System	11 Sep 2020 01:19:04
User entered 'Yes (Y)'	System	11 Sep 2020 01:19:04

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-10T21:18:29', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '8bed3312-035b-431e-8ee7-1482a596f548'	System	11 Sep 2020 01:19:04
User entered '98.0'	System	11 Sep 2020 01:19:04

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-10T21:18:35', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '8bed3312-035b-431e-8ee7-1482a596f548'	System	11 Sep 2020 01:19:04
User entered 'No (N)'	System	11 Sep 2020 01:19:04

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-10T21:18:38', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '8bed3312-035b-431e-8ee7-1482a596f548' User entered '10 Sep 2020 21:18'	System	11 Sep 2020 01:19:04
	System	11 Sep 2020 01:19:04

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	08 Sep 2020 18:52:55
User entered 'Day 4'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-12T09:36:28', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '986cd0ac-4d35-47c3-870b-0e09df7268d2'	System	12 Sep 2020 13:36:44
User entered 'Yes (Y)'	System	12 Sep 2020 13:36:44

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-12T09:36:35', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '986cd0ac-4d35-47c3-870b-0e09df7268d2' User entered '97.8'	System	12 Sep 2020 13:36:44
	System	12 Sep 2020 13:36:44

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-12T09:36:38', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '986cd0ac-4d35-47c3-870b-0e09df7268d2'	System	12 Sep 2020 13:36:44
User entered 'No (N)'	System	12 Sep 2020 13:36:44

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-12T09:36:41', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '986cd0ac-4d35-47c3-870b-0e09df7268d2' User entered '12 Sep 2020 09:36'	System	12 Sep 2020 13:36:44
	System	12 Sep 2020 13:36:44

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	08 Sep 2020 18:52:55
User entered 'Day 5'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-13T07:10:52', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '6aa45944-bd89-4315-91b4-04dd55eaf412' User entered 'Yes (Y)'	System	13 Sep 2020 11:11:13
	System	13 Sep 2020 11:11:13

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-13T07:11:01', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '6aa45944-bd89-4315-91b4-04dd55eaf412' User entered '98.2'	System	13 Sep 2020 11:11:13
	System	13 Sep 2020 11:11:13

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-13T07:11:06', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '6aa45944-bd89-4315-91b4-04dd55eaf412'	System	13 Sep 2020 11:11:13
User entered 'No (N)'	System	13 Sep 2020 11:11:13

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-13T07:11:10', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '6aa45944-bd89-4315-91b4-04dd55eaf412' User entered '13 Sep 2020 07:11'	System	13 Sep 2020 11:11:13
	System	13 Sep 2020 11:11:13

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	08 Sep 2020 18:52:55
User entered 'Day 6'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-14T08:24:57', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'd9e6e172-8ae1-4520-a941-00b6b03d49b9' User entered 'No (N)'	System	14 Sep 2020 12:25:06
	System	14 Sep 2020 12:25:06

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-14T08:25:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'd9e6e172-8ae1-4520-a941-00b6b03d49b9' User entered 'No (N)'	System	14 Sep 2020 12:25:06
	System	14 Sep 2020 12:25:06

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-14T08:25:03', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'd9e6e172-8ae1-4520-a941-00b6b03d49b9' User entered '14 Sep 2020 08:25'	System	14 Sep 2020 12:25:06
	System	14 Sep 2020 12:25:06

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	08 Sep 2020 18:52:55
User entered 'Day 7'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-15T09:16:27', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '4c42db91-bb92-4b80-ba8a-1f8b46a1bf4e' User entered 'Yes (Y)'	System	15 Sep 2020 13:16:42
	System	15 Sep 2020 13:16:42

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-15T09:16:33', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '4c42db91-bb92-4b80-ba8a-1f8b46a1bf4e' User entered '98.2'	System	15 Sep 2020 13:16:42
	System	15 Sep 2020 13:16:42

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-15T09:16:36', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '4c42db91-bb92-4b80-ba8a-1f8b46a1bf4e' User entered 'No (N)'	System	15 Sep 2020 13:16:42
	System	15 Sep 2020 13:16:42

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-15T09:16:39', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '4c42db91-bb92-4b80-ba8a-1f8b46a1bf4e'	System	15 Sep 2020 13:16:42
User entered '15 Sep 2020 09:16'	System	15 Sep 2020 13:16:42

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	08 Sep 2020 18:52:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T15:01:01', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'bbbd875c-0fce-49d7-b1ba-a1e27acfca12'	System	08 Sep 2020 19:01:17
User entered 'None (1)'	System	08 Sep 2020 19:01:17

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T15:01:06', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'bbbd875c-0fce-49d7-b1ba-a1e27acfca12'	System	08 Sep 2020 19:01:17
User entered 'No (N)'	System	08 Sep 2020 19:01:17

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T15:01:09', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'bbbd875c-0fce-49d7-b1ba-a1e27acfca12'	System	08 Sep 2020 19:01:17
User entered 'No (N)'	System	08 Sep 2020 19:01:17

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T15:01:12', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'bbbd875c-0fce-49d7-b1ba-a1e27acfca12'	System	08 Sep 2020 19:01:17
User entered 'None (1)'	System	08 Sep 2020 19:01:17

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T15:01:15', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'bbbd875c-0fce-49d7-b1ba-a1e27acfca12' User entered '08 Sep 2020 15:01'	System	08 Sep 2020 19:01:17
	System	08 Sep 2020 19:01:17

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '08 Sep 2020 14:47'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '08 Sep 2020 17:17'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	08 Sep 2020 18:52:55
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T20:06:20', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '16e05eb9-91a7-4020-b00f-ef96d8fc038a'	System	09 Sep 2020 00:06:35
User entered 'None (1)'	System	09 Sep 2020 00:06:35

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T20:06:23', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '16e05eb9-91a7-4020-b00f-ef96d8fc038a'	System	09 Sep 2020 00:06:35
User entered 'No (N)'	System	09 Sep 2020 00:06:35

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T20:06:25', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '16e05eb9-91a7-4020-b00f-ef96d8fc038a' User entered 'No (N)'	System	09 Sep 2020 00:06:35
	System	09 Sep 2020 00:06:35

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T20:06:28', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '16e05eb9-91a7-4020-b00f-ef96d8fc038a'	System	09 Sep 2020 00:06:35
User entered 'None (1)'	System	09 Sep 2020 00:06:35

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T20:06:30', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '16e05eb9-91a7-4020-b00f-ef96d8fc038a' User entered '08 Sep 2020 20:06'	System	09 Sep 2020 00:06:35
	System	09 Sep 2020 00:06:35

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '08 Sep 2020 18:12'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	08 Sep 2020 18:52:55
User entered 'Day 2'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-09T17:45:35', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '393b41eb-b57d-46a0-a141-685289e1de8a' User entered 'None (1)'	System	09 Sep 2020 21:45:50
	System	09 Sep 2020 21:45:50

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-09T17:45:38', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '393b41eb-b57d-46a0-a141-685289e1de8a' User entered 'No (N)'	System	09 Sep 2020 21:45:50
	System	09 Sep 2020 21:45:50

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-09T17:45:42', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '393b41eb-b57d-46a0-a141-685289e1de8a' User entered 'No (N)'	System	09 Sep 2020 21:45:50
	System	09 Sep 2020 21:45:50

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-09T17:45:45', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '393b41eb-b57d-46a0-a141-685289e1de8a' User entered 'None (1)'	System	09 Sep 2020 21:45:50
	System	09 Sep 2020 21:45:50

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-09T17:45:47', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '393b41eb-b57d-46a0-a141-685289e1de8a' User entered '09 Sep 2020 17:45'	System	09 Sep 2020 21:45:50
	System	09 Sep 2020 21:45:50

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	08 Sep 2020 18:52:55
User entered 'Day 3'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-10T21:18:44', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'a4fc0c05-e33d-4389-972a-443be5f6b514'	System	11 Sep 2020 01:19:29
User entered 'None (1)'	System	11 Sep 2020 01:19:29

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-10T21:18:47', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'a4fc0c05-e33d-4389-972a-443be5f6b514'	System	11 Sep 2020 01:19:29
User entered 'No (N)'	System	11 Sep 2020 01:19:29

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-10T21:18:50', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'a4fc0c05-e33d-4389-972a-443be5f6b514'	System	11 Sep 2020 01:19:29
User entered 'No (N)'	System	11 Sep 2020 01:19:29

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-10T21:18:54', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'a4fc0c05-e33d-4389-972a-443be5f6b514'	System	11 Sep 2020 01:19:29
User entered 'None (1)'	System	11 Sep 2020 01:19:29

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-10T21:18:57', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'a4fc0c05-e33d-4389-972a-443be5f6b514' User entered '10 Sep 2020 21:18'	System	11 Sep 2020 01:19:29
	System	11 Sep 2020 01:19:29

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	08 Sep 2020 18:52:55
User entered 'Day 4'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-12T09:36:45', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '818cbcf4-d137-478c-82e3-8d853d51e34c'	System	12 Sep 2020 13:36:56
User entered 'None (1)'	System	12 Sep 2020 13:36:56

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-12T09:36:47', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '818cbcf4-d137-478c-82e3-8d853d51e34c' User entered 'No (N)'	System	12 Sep 2020 13:36:56
	System	12 Sep 2020 13:36:56

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-12T09:36:50', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '818cbcf4-d137-478c-82e3-8d853d51e34c' User entered 'No (N)'	System	12 Sep 2020 13:36:56
	System	12 Sep 2020 13:36:56

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-12T09:36:52', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '818cbcf4-d137-478c-82e3-8d853d51e34c' User entered 'None (1)'	System	12 Sep 2020 13:36:56
	System	12 Sep 2020 13:36:56

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-12T09:36:55', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '818cbcf4-d137-478c-82e3-8d853d51e34c' User entered '12 Sep 2020 09:36'	System	12 Sep 2020 13:36:56
	System	12 Sep 2020 13:36:56

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	08 Sep 2020 18:52:55
User entered 'Day 5'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-13T07:11:15', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'aa8413e3-e1c2-4438-a44b-5b59cdef45f2'	System	13 Sep 2020 11:11:30
User entered 'None (1)'	System	13 Sep 2020 11:11:30

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-13T07:11:18', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'aa8413e3-e1c2-4438-a44b-5b59cdef45f2'	System	13 Sep 2020 11:11:30
User entered 'No (N)'	System	13 Sep 2020 11:11:30

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-13T07:11:20', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'aa8413e3-e1c2-4438-a44b-5b59cdef45f2'	System	13 Sep 2020 11:11:30
User entered 'No (N)'	System	13 Sep 2020 11:11:30

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-13T07:11:23', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'aa8413e3-e1c2-4438-a44b-5b59cdef45f2'	System	13 Sep 2020 11:11:30
User entered 'None (1)'	System	13 Sep 2020 11:11:30

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-13T07:11:25', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'aa8413e3-e1c2-4438-a44b-5b59cdef45f2'	System	13 Sep 2020 11:11:30
User entered '13 Sep 2020 07:11'	System	13 Sep 2020 11:11:30

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	08 Sep 2020 18:52:55
User entered 'Day 6'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-14T08:25:07', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'e98bb62d-6185-4aa4-b631-cd90b3ee3e16' User entered 'None (1)'	System	14 Sep 2020 12:25:20
	System	14 Sep 2020 12:25:20

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-14T08:25:10', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'e98bb62d-6185-4aa4-b631-cd90b3ee3e16' User entered 'No (N)'	System	14 Sep 2020 12:25:20
	System	14 Sep 2020 12:25:20

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-14T08:25:13', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'e98bb62d-6185-4aa4-b631-cd90b3ee3e16' User entered 'No (N)'	System	14 Sep 2020 12:25:20
	System	14 Sep 2020 12:25:20

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-14T08:25:15', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'e98bb62d-6185-4aa4-b631-cd90b3ee3e16' User entered 'None (1)'	System	14 Sep 2020 12:25:20
	System	14 Sep 2020 12:25:20

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-14T08:25:18', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'e98bb62d-6185-4aa4-b631-cd90b3ee3e16' User entered '14 Sep 2020 08:25'	System	14 Sep 2020 12:25:20
	System	14 Sep 2020 12:25:20

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	08 Sep 2020 18:52:55
User entered 'Day 7'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-15T09:16:45', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'ef88d53b-13b9-4c82-8f4e-172e33e7550f' User entered 'None (1)'	System	15 Sep 2020 13:16:58
	System	15 Sep 2020 13:16:58

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-15T09:16:47', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'ef88d53b-13b9-4c82-8f4e-172e33e7550f' User entered 'No (N)'	System	15 Sep 2020 13:16:58
	System	15 Sep 2020 13:16:58

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-15T09:16:50', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'ef88d53b-13b9-4c82-8f4e-172e33e7550f' User entered 'No (N)'	System	15 Sep 2020 13:16:58
	System	15 Sep 2020 13:16:58

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-15T09:16:52', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'ef88d53b-13b9-4c82-8f4e-172e33e7550f' User entered 'None (1)'	System	15 Sep 2020 13:16:58
	System	15 Sep 2020 13:16:58

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-15T09:16:54', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'ef88d53b-13b9-4c82-8f4e-172e33e7550f' User entered '15 Sep 2020 09:16'	System	15 Sep 2020 13:16:58
	System	15 Sep 2020 13:16:58

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	08 Sep 2020 18:52:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T15:01:20', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '75750331-c9e0-45e3-ac79-2695b69973fd' User entered 'None (0)'	System	08 Sep 2020 19:01:42
	System	08 Sep 2020 19:01:42

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T15:01:22', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '75750331-c9e0-45e3-ac79-2695b69973fd' User entered 'None (0)'	System	08 Sep 2020 19:01:42
	System	08 Sep 2020 19:01:42

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T15:01:25', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '75750331-c9e0-45e3-ac79-2695b69973fd' User entered 'None (0)'	System	08 Sep 2020 19:01:42
	System	08 Sep 2020 19:01:42

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T15:01:27', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '75750331-c9e0-45e3-ac79-2695b69973fd' User entered 'None (0)'	System	08 Sep 2020 19:01:42
	System	08 Sep 2020 19:01:42

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T15:01:29', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '75750331-c9e0-45e3-ac79-2695b69973fd' User entered 'None (0)'	System	08 Sep 2020 19:01:42
	System	08 Sep 2020 19:01:42

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T15:01:31', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '75750331-c9e0-45e3-ac79-2695b69973fd' User entered 'None (0)'	System	08 Sep 2020 19:01:42
	System	08 Sep 2020 19:01:42

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

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)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T15:01:35', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '75750331-c9e0-45e3-ac79-2695b69973fd' User entered 'No (N)'	System	08 Sep 2020 19:01:42
	System	08 Sep 2020 19:01:42

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T15:01:38', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '75750331-c9e0-45e3-ac79-2695b69973fd' User entered '08 Sep 2020 15:01'	System	08 Sep 2020 19:01:42
	System	08 Sep 2020 19:01:42

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '08 Sep 2020 14:47'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '08 Sep 2020 17:17'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	08 Sep 2020 18:52:55
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T20:06:35', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '01a7776e-f8ff-4e64-abb0-79b03fa48618' User entered 'None (0)'	System	09 Sep 2020 00:06:53
	System	09 Sep 2020 00:06:53

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T20:06:37', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '01a7776e-f8ff-4e64-abb0-79b03fa48618' User entered 'None (0)'	System	09 Sep 2020 00:06:53
	System	09 Sep 2020 00:06:53

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T20:06:39', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '01a7776e-f8ff-4e64-abb0-79b03fa48618' User entered 'None (0)'	System	09 Sep 2020 00:06:53
	System	09 Sep 2020 00:06:53

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T20:06:41', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '01a7776e-f8ff-4e64-abb0-79b03fa48618' User entered 'None (0)'	System	09 Sep 2020 00:06:53
	System	09 Sep 2020 00:06:53

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T20:06:43', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '01a7776e-f8ff-4e64-abb0-79b03fa48618' User entered 'None (0)'	System	09 Sep 2020 00:06:53
	System	09 Sep 2020 00:06:53

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T20:06:45', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '01a7776e-f8ff-4e64-abb0-79b03fa48618' User entered 'None (0)'	System	09 Sep 2020 00:06:53
	System	09 Sep 2020 00:06:53

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

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)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T20:06:48', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '01a7776e-f8ff-4e64-abb0-79b03fa48618' User entered 'No (N)'	System	09 Sep 2020 00:06:53
	System	09 Sep 2020 00:06:53

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-08T20:06:50', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '01a7776e-f8ff-4e64-abb0-79b03fa48618' User entered '08 Sep 2020 20:06'	System	09 Sep 2020 00:06:53
	System	09 Sep 2020 00:06:53

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '08 Sep 2020 18:12'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	08 Sep 2020 18:52:55
User entered 'Day 2'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-09T17:45:53', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '8380c7f7-db01-4aa5-adaa-6e82b901fbf7' User entered 'None (0)'	System	09 Sep 2020 21:46:18
	System	09 Sep 2020 21:46:18

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-09T17:45:55', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '8380c7f7-db01-4aa5-adaa-6e82b901fbf7' User entered 'None (0)'	System	09 Sep 2020 21:46:18
	System	09 Sep 2020 21:46:18

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-09T17:45:58', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '8380c7f7-db01-4aa5-adaa-6e82b901fbf7' User entered 'None (0)'	System	09 Sep 2020 21:46:18
	System	09 Sep 2020 21:46:18

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-09T17:46:01', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '8380c7f7-db01-4aa5-adaa-6e82b901fbf7' User entered 'None (0)'	System	09 Sep 2020 21:46:18
	System	09 Sep 2020 21:46:18

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-09T17:46:05', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '8380c7f7-db01-4aa5-adaa-6e82b901fbf7' User entered 'None (0)'	System	09 Sep 2020 21:46:18
	System	09 Sep 2020 21:46:18

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-09T17:46:07', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '8380c7f7-db01-4aa5-adaa-6e82b901fbf7' User entered 'None (0)'	System	09 Sep 2020 21:46:18
	System	09 Sep 2020 21:46:18

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:41

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)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-09T17:46:12', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '8380c7f7-db01-4aa5-adaa-6e82b901fbf7'	System	09 Sep 2020 21:46:18
User entered 'No (N)'	System	09 Sep 2020 21:46:18

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-09T17:46:15', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '8380c7f7-db01-4aa5-adaa-6e82b901fbf7' User entered '09 Sep 2020 17:46'	System	09 Sep 2020 21:46:18
	System	09 Sep 2020 21:46:18

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	08 Sep 2020 18:52:55
User entered 'Day 3'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-10T21:19:02', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'af2536a1-6946-43b9-b303-52724b5a6001' User entered 'None (0)'	System	11 Sep 2020 01:19:31
	System	11 Sep 2020 01:19:31

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-10T21:19:05', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'af2536a1-6946-43b9-b303-52724b5a6001' User entered 'None (0)'	System	11 Sep 2020 01:19:31
	System	11 Sep 2020 01:19:31

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-10T21:19:08', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'af2536a1-6946-43b9-b303-52724b5a6001' User entered 'None (0)'	System	11 Sep 2020 01:19:31
	System	11 Sep 2020 01:19:31

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-10T21:19:11', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'af2536a1-6946-43b9-b303-52724b5a6001' User entered 'None (0)'	System	11 Sep 2020 01:19:31
	System	11 Sep 2020 01:19:31

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-10T21:19:14', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'af2536a1-6946-43b9-b303-52724b5a6001' User entered 'None (0)'	System	11 Sep 2020 01:19:31
	System	11 Sep 2020 01:19:31

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-10T21:19:16', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'af2536a1-6946-43b9-b303-52724b5a6001' User entered 'None (0)'	System	11 Sep 2020 01:19:31
	System	11 Sep 2020 01:19:31

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:41

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)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-10T21:19:19', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'af2536a1-6946-43b9-b303-52724b5a6001' User entered 'No (N)'	System	11 Sep 2020 01:19:31
	System	11 Sep 2020 01:19:31

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-10T21:19:22', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'af2536a1-6946-43b9-b303-52724b5a6001' User entered '10 Sep 2020 21:19'	System	11 Sep 2020 01:19:31
	System	11 Sep 2020 01:19:31

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	08 Sep 2020 18:52:55
User entered 'Day 4'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-12T09:36:58', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'dd976c02-bd9b-4079-a154-7848f1bec3b1' User entered 'None (0)'	System	12 Sep 2020 13:37:19
	System	12 Sep 2020 13:37:19

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-12T09:37:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'dd976c02-bd9b-4079-a154-7848f1bec3b1' User entered 'None (0)'	System	12 Sep 2020 13:37:19
	System	12 Sep 2020 13:37:19

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-12T09:37:03', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'dd976c02-bd9b-4079-a154-7848f1bec3b1' User entered 'None (0)'	System	12 Sep 2020 13:37:19
	System	12 Sep 2020 13:37:19

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-12T09:37:05', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'dd976c02-bd9b-4079-a154-7848f1bec3b1' User entered 'None (0)'	System	12 Sep 2020 13:37:19
	System	12 Sep 2020 13:37:19

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-12T09:37:07', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'dd976c02-bd9b-4079-a154-7848f1bec3b1' User entered 'None (0)'	System	12 Sep 2020 13:37:19
	System	12 Sep 2020 13:37:19

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-12T09:37:09', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'dd976c02-bd9b-4079-a154-7848f1bec3b1' User entered 'None (0)'	System	12 Sep 2020 13:37:19
	System	12 Sep 2020 13:37:19

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:41

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)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-12T09:37:13', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'dd976c02-bd9b-4079-a154-7848f1bec3b1' User entered 'No (N)'	System	12 Sep 2020 13:37:19
	System	12 Sep 2020 13:37:19

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-12T09:37:15', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'dd976c02-bd9b-4079-a154-7848f1bec3b1' User entered '12 Sep 2020 09:37'	System	12 Sep 2020 13:37:19
	System	12 Sep 2020 13:37:19

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	08 Sep 2020 18:52:55
User entered 'Day 5'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-13T07:11:30', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '5eaa0f20-d9d5-4748-b1a1-5f2d2ee04de9' User entered 'None (0)'	System	13 Sep 2020 11:11:51
	System	13 Sep 2020 11:11:51

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-13T07:11:33', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '5eaa0f20-d9d5-4748-b1a1-5f2d2ee04de9' User entered 'None (0)'	System	13 Sep 2020 11:11:51
	System	13 Sep 2020 11:11:51

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-13T07:11:35', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '5eaa0f20-d9d5-4748-b1a1-5f2d2ee04de9' User entered 'None (0)'	System	13 Sep 2020 11:11:51
	System	13 Sep 2020 11:11:51

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-13T07:11:37', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '5eaa0f20-d9d5-4748-b1a1-5f2d2ee04de9' User entered 'None (0)'	System	13 Sep 2020 11:11:51
	System	13 Sep 2020 11:11:51

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-13T07:11:40', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '5eaa0f20-d9d5-4748-b1a1-5f2d2ee04de9' User entered 'None (0)'	System	13 Sep 2020 11:11:51
	System	13 Sep 2020 11:11:51

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-13T07:11:42', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '5eaa0f20-d9d5-4748-b1a1-5f2d2ee04de9' User entered 'None (0)'	System	13 Sep 2020 11:11:51
	System	13 Sep 2020 11:11:51

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:41

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)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-13T07:11:46', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '5eaa0f20-d9d5-4748-b1a1-5f2d2ee04de9' User entered 'No (N)'	System	13 Sep 2020 11:11:51
	System	13 Sep 2020 11:11:51

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-13T07:11:48', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '5eaa0f20-d9d5-4748-b1a1-5f2d2ee04de9' User entered '13 Sep 2020 07:11'	System	13 Sep 2020 11:11:51
	System	13 Sep 2020 11:11:51

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	08 Sep 2020 18:52:55
User entered 'Day 6'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-14T08:25:22', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'dd73697e-a0e7-44cd-91e6-2197bfd28729' User entered 'None (0)'	System	14 Sep 2020 12:25:38
	System	14 Sep 2020 12:25:38

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-14T08:25:24', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'dd73697e-a0e7-44cd-91e6-2197bfd28729' User entered 'None (0)'	System	14 Sep 2020 12:25:38
	System	14 Sep 2020 12:25:38

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-14T08:25:26', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'dd73697e-a0e7-44cd-91e6-2197bfd28729' User entered 'None (0)'	System	14 Sep 2020 12:25:38
	System	14 Sep 2020 12:25:38

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-14T08:25:27', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'dd73697e-a0e7-44cd-91e6-2197bfd28729' User entered 'None (0)'	System	14 Sep 2020 12:25:38
	System	14 Sep 2020 12:25:38

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-14T08:25:30', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'dd73697e-a0e7-44cd-91e6-2197bfd28729' User entered 'None (0)'	System	14 Sep 2020 12:25:38
	System	14 Sep 2020 12:25:38

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-14T08:25:32', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'dd73697e-a0e7-44cd-91e6-2197bfd28729' User entered 'None (0)'	System	14 Sep 2020 12:25:38
	System	14 Sep 2020 12:25:38

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:41

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)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-14T08:25:35', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'dd73697e-a0e7-44cd-91e6-2197bfd28729' User entered 'No (N)'	System	14 Sep 2020 12:25:38
	System	14 Sep 2020 12:25:38

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-14T08:25:37', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'dd73697e-a0e7-44cd-91e6-2197bfd28729' User entered '14 Sep 2020 08:25'	System	14 Sep 2020 12:25:38
	System	14 Sep 2020 12:25:38

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	08 Sep 2020 18:52:55
User entered 'Day 7'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-15T09:16:57', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '14a1f31b-e0d5-4be4-af1f-8ec94ff02c2f' User entered 'None (0)'	System	15 Sep 2020 13:17:13
	System	15 Sep 2020 13:17:13

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-15T09:16:59', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '14a1f31b-e0d5-4be4-af1f-8ec94ff02c2f' User entered 'None (0)'	System	15 Sep 2020 13:17:13
	System	15 Sep 2020 13:17:13

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-15T09:17:01', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '14a1f31b-e0d5-4be4-af1f-8ec94ff02c2f' User entered 'None (0)'	System	15 Sep 2020 13:17:13
	System	15 Sep 2020 13:17:13

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-15T09:17:03', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '14a1f31b-e0d5-4be4-af1f-8ec94ff02c2f' User entered 'None (0)'	System	15 Sep 2020 13:17:13
	System	15 Sep 2020 13:17:13

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-15T09:17:04', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '14a1f31b-e0d5-4be4-af1f-8ec94ff02c2f' User entered 'None (0)'	System	15 Sep 2020 13:17:13
	System	15 Sep 2020 13:17:13

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-15T09:17:06', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '14a1f31b-e0d5-4be4-af1f-8ec94ff02c2f' User entered 'None (0)'	System	15 Sep 2020 13:17:13
	System	15 Sep 2020 13:17:13

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:41

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)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-15T09:17:08', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '14a1f31b-e0d5-4be4-af1f-8ec94ff02c2f' User entered 'No (N)'	System	15 Sep 2020 13:17:13
	System	15 Sep 2020 13:17:13

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-09-15T09:17:11', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '14a1f31b-e0d5-4be4-af1f-8ec94ff02c2f' User entered '15 Sep 2020 09:17'	System	15 Sep 2020 13:17:13
	System	15 Sep 2020 13:17:13

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:52:55

US3722215

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:35:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:52:55

US3722215

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Kayla Peay (b) (4)	15 Sep 2020 19:44:45

US3722215

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '15 Sep 2020'	Kayla Peay (b) (4)	15 Sep 2020 19:44:45

US3722215

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	15 Sep 2020 19:44:45

US3722215

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered empty.	Kayla Peay (b) (4)	15 Sep 2020 19:44:45

US3722215

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Kayla Peay (b) (4)	15 Sep 2020 19:44:50

US3722215

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User entered 'I'	System	15 Sep 2020 19:44:50

US3722215

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Kayla Peay (b) (4)	22 Sep 2020 20:11:13

US3722215

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '22 Sep 2020'	Kayla Peay (b) (4)	22 Sep 2020 20:11:13

US3722215

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	22 Sep 2020 20:11:13

US3722215

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered empty.	Kayla Peay (b) (4)	22 Sep 2020 20:11:13

US3722215

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Kayla Peay (b) (4)	22 Sep 2020 20:11:15

US3722215

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User entered 'I'	System	22 Sep 2020 20:11:15

US3722215

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Kayla Peay (b) (4)	30 Sep 2020 12:32:13

US3722215

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '29 Sep 2020'	Kayla Peay (b) (4)	30 Sep 2020 12:32:13

US3722215

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	30 Sep 2020 12:32:13

US3722215

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered empty.	Kayla Peay (b) (4)	30 Sep 2020 12:32:13

US3722215

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Kayla Peay (b) (4)	30 Sep 2020 12:32:16

US3722215

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User entered 'I'	System	30 Sep 2020 12:32:16

US3722215

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Kayla Peay (b) (4)	05 Oct 2020 20:41:14

US3722215

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '5 Oct 2020'	Kayla Peay (b) (4)	05 Oct 2020 20:41:14

US3722215

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Clinic (Clinic)'	Kayla Peay (b) (4)	05 Oct 2020 20:41:14

US3722215

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User entered 'VISIT3'	System	05 Oct 2020 20:41:14

US3722215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Kayla Peay (b) (4)	05 Oct 2020 20:41:40

US3722215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '5 Oct 2020'	Kayla Peay (b) (4)	05 Oct 2020 20:41:40

US3722215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '16:28'	Kayla Peay (b) (4)	05 Oct 2020 20:41:40

US3722215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User entered '5 Oct 2020 16:28'	System	05 Oct 2020 20:41:40

US3722215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '97.7' F	Kayla Peay (b) (4)	05 Oct 2020 20:41:40

US3722215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	05 Oct 2020 20:41:40

US3722215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered empty.	Kayla Peay (b) (4)	05 Oct 2020 20:41:40

US3722215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '58'	Kayla Peay (b) (4)	05 Oct 2020 20:41:40

US3722215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User entered 'bpm'	System	05 Oct 2020 20:41:40

US3722215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '18'	Kayla Peay (b) (4)	05 Oct 2020 20:41:40

US3722215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User entered 'breaths/min'	System	05 Oct 2020 20:41:40

US3722215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '154'	Kayla Peay (b) (4)	05 Oct 2020 20:41:40

US3722215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User entered 'mmHg'	System	05 Oct 2020 20:41:40

US3722215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '84'	Kayla Peay (b) (4)	05 Oct 2020 20:41:40

US3722215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User entered 'mmHg'	System	05 Oct 2020 20:41:40

US3722215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49

US3722215

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49

US3722215

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:35:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Kayla Peay (b) (4)	05 Oct 2020 20:41:46

US3722215

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:35:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '5 Oct 2020'	Kayla Peay (b) (4)	05 Oct 2020 20:41:46

US3722215

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Kayla Peay (b) (4)	05 Oct 2020 20:41:54

US3722215

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '5 Oct 2020'	Kayla Peay (b) (4)	05 Oct 2020 20:41:54

US3722215

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered '16:36'	Kayla Peay (b) (4)	05 Oct 2020 20:41:54

US3722215

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User entered '5 Oct 2020 16:36'	System	05 Oct 2020 20:41:54

US3722215

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 14:52:32
User entered 'Yes (Y)'	Kayla Peay (b) (4)	05 Oct 2020 20:41:56

US3722215

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:49
User entered 'I'	System	05 Oct 2020 20:41:56

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 64'	System	12 Aug 2020 19:12:24

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-10-15T17:01:18', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'c5c47156-daf5-4a9f-a453-e713293555b5'	System	15 Oct 2020 21:01:28
User entered 'No (N)'	System	15 Oct 2020 21:01:28

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

Have you been exposed to someone with 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)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-10-15T17:01:22', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'c5c47156-daf5-4a9f-a453-e713293555b5'	System	15 Oct 2020 21:01:28
User entered 'No (N)'	System	15 Oct 2020 21:01:28

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-10-15T17:01:25', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'c5c47156-daf5-4a9f-a453-e713293555b5' User entered '15 Oct 2020 17:01:25'	System	15 Oct 2020 21:01:28
	System	15 Oct 2020 21:01:28

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered '12 Oct 2020 00:01'	System	12 Aug 2020 19:12:24

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered '16 Oct 2020 23:59'	System	12 Aug 2020 19:12:24

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 71'	System	12 Aug 2020 19:12:24

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-10-19T06:43:08', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '70e86cc5-8fda-48f9-ba8f-ae30b88b3c19'	System	19 Oct 2020 10:43:22
User entered 'No (N)'	System	19 Oct 2020 10:43:22

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

Have you been exposed to someone with 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)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-10-19T06:43:12', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '70e86cc5-8fda-48f9-ba8f-ae30b88b3c19'	System	19 Oct 2020 10:43:22
User entered 'No (N)'	System	19 Oct 2020 10:43:22

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-10-19T06:43:19', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '70e86cc5-8fda-48f9-ba8f-ae30b88b3c19' User entered '19 Oct 2020 06:43:19'	System	19 Oct 2020 10:43:22
	System	19 Oct 2020 10:43:22

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered '19 Oct 2020 00:01'	System	12 Aug 2020 19:12:24

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered '23 Oct 2020 23:59'	System	12 Aug 2020 19:12:24

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 78'	System	12 Aug 2020 19:12:24

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[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)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-10-28T12:00:31', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'f480503d-b42a-4d69-bb3e-59a70b85d211'	System	28 Oct 2020 16:00:51
User entered 'No (N)'	System	28 Oct 2020 16:00:51

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

Have you been exposed to someone with 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)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-10-28T12:00:35', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'f480503d-b42a-4d69-bb3e-59a70b85d211'	System	28 Oct 2020 16:00:51
User entered 'No (N)'	System	28 Oct 2020 16:00:51

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AF9F3E76-81C8-45B0-BFA8-3BB7CE1A792E)', Time: '2020-10-28T12:00:39', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'f480503d-b42a-4d69-bb3e-59a70b85d211' User entered '28 Oct 2020 12:00:39'	System	28 Oct 2020 16:00:51
	System	28 Oct 2020 16:00:51

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered '26 Oct 2020 00:01'	System	12 Aug 2020 19:12:24

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:04:05
Data entry locked.	System	12 Aug 2020 19:12:24
User entered '30 Oct 2020 23:59'	System	12 Aug 2020 19:12:24

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 92'	System	12 Aug 2020 19:12:24

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[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)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

Have you been exposed to someone with 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)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36
Data entry locked.	System	12 Aug 2020 19:12:24
User entered '09 Nov 2020 00:01'	System	12 Aug 2020 19:12:24

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36
Data entry locked.	System	12 Aug 2020 19:12:24
User entered '13 Nov 2020 23:59'	System	12 Aug 2020 19:12:24

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36
Data entry locked.	System	12 Aug 2020 19:12:24
User entered 'Day 99'	System	12 Aug 2020 19:12:24

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[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)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

Have you been exposed to someone with 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)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36
Data entry locked.	System	12 Aug 2020 19:12:24
User entered '16 Nov 2020 00:01'	System	12 Aug 2020 19:12:24

US3722215

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:15:36
Data entry locked.	System	12 Aug 2020 19:12:24
User entered '20 Nov 2020 23:59'	System	12 Aug 2020 19:12:24

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2020-12-14T14:26:03', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '6b49e6ca-1f72-4cd9-a81e-1275b6f01571' User entered 'No (N)'	System	14 Dec 2020 19:26:17
	System	14 Dec 2020 19:26:17

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

Have you been exposed to someone with 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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2020-12-14T14:26:08', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '6b49e6ca-1f72-4cd9-a81e-1275b6f01571' User entered 'No (N)'	System	14 Dec 2020 19:26:17
	System	14 Dec 2020 19:26:17

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2020-12-14T14:26:12', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '6b49e6ca-1f72-4cd9-a81e-1275b6f01571' User entered '14 Dec 2020 14:26:12'	System	14 Dec 2020 19:26:17
	System	14 Dec 2020 19:26:17

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2020-12-22T09:01:11', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '6211c1e3-a1e8-47ef-9b29-59523e9cc5c9' User entered 'No (N)'	System	22 Dec 2020 14:01:19
	System	22 Dec 2020 14:01:19

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

Have you been exposed to someone with 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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2020-12-22T09:01:14', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '6211c1e3-a1e8-47ef-9b29-59523e9cc5c9' User entered 'No (N)'	System	22 Dec 2020 14:01:19
	System	22 Dec 2020 14:01:19

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2020-12-22T09:01:17', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '6211c1e3-a1e8-47ef-9b29-59523e9cc5c9' User entered '22 Dec 2020 09:01:17'	System	22 Dec 2020 14:01:19
	System	22 Dec 2020 14:01:19

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2020-12-27T12:17:18', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '3d1c3158-5f62-447c-bd6d-cd93902d35d3' User entered 'No (N)'	System	27 Dec 2020 17:17:26
	System	27 Dec 2020 17:17:26

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

Have you been exposed to someone with 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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2020-12-27T12:17:21', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '3d1c3158-5f62-447c-bd6d-cd93902d35d3' User entered 'No (N)'	System	27 Dec 2020 17:17:26

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2020-12-27T12:17:23', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '3d1c3158-5f62-447c-bd6d-cd93902d35d3' User entered '27 Dec 2020 12:17:23'	System	27 Dec 2020 17:17:26
	System	27 Dec 2020 17:17:26

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-01-02T14:42:17', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'eeecd3a8-a848-4421-afeb-7f58104c860e' User entered 'No (N)'	System	02 Jan 2021 19:42:49
	System	02 Jan 2021 19:42:49

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

Have you been exposed to someone with 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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-01-02T14:42:31', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'eeecd3a8-a848-4421-afeb-7f58104c860e' User entered 'Yes (Y)'	System	02 Jan 2021 19:42:49
	System	02 Jan 2021 19:42:49

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Please 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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-01-02T14:42:37', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'eeecd3a8-a848-4421-afeb-7f58104c860e'	System	02 Jan 2021 19:42:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Jan 2021 19:42:49

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-01-02T14:42:41', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'eeecd3a8-a848-4421-afeb-7f58104c860e' User entered '02 Jan 2021 14:42:41'	System	02 Jan 2021 19:42:49
	System	02 Jan 2021 19:42:49

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-01-08T15:23:26', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'fe80a424-dcdd-47e5-aed6-4fda17895e8a'	System	08 Jan 2021 20:23:57
User entered 'No (N)'	System	08 Jan 2021 20:23:57

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

Have you been exposed to someone with 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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-01-08T15:23:43', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'fe80a424-dcdd-47e5-aed6-4fda17895e8a'	System	08 Jan 2021 20:23:57
User entered 'No (N)'	System	08 Jan 2021 20:23:57

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-01-08T15:23:54', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'fe80a424-dcdd-47e5-aed6-4fda17895e8a' User entered '08 Jan 2021 15:23:54'	System	08 Jan 2021 20:23:57
	System	08 Jan 2021 20:23:57

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-01-16T13:11:52', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'c7d03877-09b3-486b-91d7-ab0b12c2f94b'	System	16 Jan 2021 18:12:01
User entered 'No (N)'	System	16 Jan 2021 18:12:01

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Have you been exposed to someone with 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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-01-16T13:11:56', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'c7d03877-09b3-486b-91d7-ab0b12c2f94b'	System	16 Jan 2021 18:12:01
User entered 'No (N)'	System	16 Jan 2021 18:12:01

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-01-16T13:11:58', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'c7d03877-09b3-486b-91d7-ab0b12c2f94b' User entered '16 Jan 2021 13:11:58'	System	16 Jan 2021 18:12:01
	System	16 Jan 2021 18:12:01

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-01-25T18:20:53', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '500b7a54-5e34-4863-a2dd-19b333de170d' User entered 'No (N)'	System	25 Jan 2021 23:21:00
	System	25 Jan 2021 23:21:00

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

Have you been exposed to someone with 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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-01-25T18:20:55', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '500b7a54-5e34-4863-a2dd-19b333de170d' User entered 'No (N)'	System	25 Jan 2021 23:21:00

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-01-25T18:20:58', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '500b7a54-5e34-4863-a2dd-19b333de170d' User entered '25 Jan 2021 18:20:58'	System	25 Jan 2021 23:21:00
	System	25 Jan 2021 23:21:00

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-01-30T14:14:24', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '617a43cf-0431-4908-8a1d-488ee21ed801' User entered 'No (N)'	System	30 Jan 2021 19:14:31
	System	30 Jan 2021 19:14:31

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Have you been exposed to someone with 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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-01-30T14:14:26', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '617a43cf-0431-4908-8a1d-488ee21ed801' User entered 'No (N)'	System	30 Jan 2021 19:14:31
	System	30 Jan 2021 19:14:31

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-01-30T14:14:29', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '617a43cf-0431-4908-8a1d-488ee21ed801' User entered '30 Jan 2021 14:14:29'	System	30 Jan 2021 19:14:31
	System	30 Jan 2021 19:14:31

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-02-08T08:41:37', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '4e73a779-2cd9-40c8-95b1-ab8a96f4783a' User entered 'No (N)'	System	08 Feb 2021 13:41:49
	System	08 Feb 2021 13:41:49

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

Have you been exposed to someone with 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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-02-08T08:41:44', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '4e73a779-2cd9-40c8-95b1-ab8a96f4783a' User entered 'No (N)'	System	08 Feb 2021 13:41:49

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-02-08T08:41:46', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '4e73a779-2cd9-40c8-95b1-ab8a96f4783a' User entered '08 Feb 2021 08:41:46'	System	08 Feb 2021 13:41:49
	System	08 Feb 2021 13:41:49

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-02-12T14:41:01', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'fb61511a-cb3c-4edc-803e-5770d69cc06b'	System	12 Feb 2021 19:41:19
User entered 'No (N)'	System	12 Feb 2021 19:41:19

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

Have you been exposed to someone with 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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-02-12T14:41:07', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'fb61511a-cb3c-4edc-803e-5770d69cc06b'	System	12 Feb 2021 19:41:19
User entered 'No (N)'	System	12 Feb 2021 19:41:19

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-02-12T14:41:11', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'fb61511a-cb3c-4edc-803e-5770d69cc06b' User entered '12 Feb 2021 14:41:11'	System	12 Feb 2021 19:41:19
	System	12 Feb 2021 19:41:19

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-02-19T12:31:49', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '3549dacf-a7fb-4034-a452-01d9a5bee67f' User entered 'No (N)'	System	19 Feb 2021 17:32:01
	System	19 Feb 2021 17:32:01

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

Have you been exposed to someone with 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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-02-19T12:31:52', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '3549dacf-a7fb-4034-a452-01d9a5bee67f' User entered 'No (N)'	System	19 Feb 2021 17:32:01
	System	19 Feb 2021 17:32:01

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-02-19T12:31:55', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '3549dacf-a7fb-4034-a452-01d9a5bee67f' User entered '19 Feb 2021 12:31:55'	System	19 Feb 2021 17:32:01

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-02-26T16:04:16-05:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'ab6412fa-6c0d-4207-aea4-840587d8b22b' User entered 'No (N)'	System	26 Feb 2021 21:04:27
	System	26 Feb 2021 21:04:27

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

Have you been exposed to someone with 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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-02-26T16:04:19-05:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'ab6412fa-6c0d-4207-aea4-840587d8b22b' User entered 'No (N)'	System	26 Feb 2021 21:04:27
	System	26 Feb 2021 21:04:27

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-02-26T16:04:22-05:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'ab6412fa-6c0d-4207-aea4-840587d8b22b' User entered '26 Feb 2021 21:04:22'	System	26 Feb 2021 21:04:27
	System	26 Feb 2021 21:04:27

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-03-06T13:01:54-05:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '3b2e9007-08ee-401d-9d63-3c5b9293ccbe'	System	06 Mar 2021 18:04:34
User entered 'No (N)'	System	06 Mar 2021 18:04:34

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

Have you been exposed to someone with 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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-03-06T13:01:57-05:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '3b2e9007-08ee-401d-9d63-3c5b9293ccbe'	System	06 Mar 2021 18:04:34
User entered 'No (N)'	System	06 Mar 2021 18:04:34

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-03-06T13:02:00-05:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '3b2e9007-08ee-401d-9d63-3c5b9293ccbe' User entered '06 Mar 2021 13:02:00'	System	06 Mar 2021 18:04:34
	System	06 Mar 2021 18:04:34

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-03-12T15:33:47-05:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'aa5ecda4-3228-40a9-8b00-0923e4b5e944'	System	12 Mar 2021 20:33:59
User entered 'No (N)'	System	12 Mar 2021 20:33:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

Have you been exposed to someone with 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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-03-12T15:33:51-05:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'aa5ecda4-3228-40a9-8b00-0923e4b5e944'	System	12 Mar 2021 20:33:59
User entered 'No (N)'	System	12 Mar 2021 20:33:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-03-12T15:33:55-05:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'aa5ecda4-3228-40a9-8b00-0923e4b5e944' User entered '12 Mar 2021 15:33:55'	System	12 Mar 2021 20:33:59
	System	12 Mar 2021 20:33:59

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-03-19T15:46:55-04:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '03a90216-16bc-4464-b95a-07d651aaa0f5'	System	19 Mar 2021 19:47:29
User entered 'Yes (Y)'	System	19 Mar 2021 19:47:29

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

Have you been exposed to someone with 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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-03-19T15:47:01-04:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '03a90216-16bc-4464-b95a-07d651aaa0f5'	System	19 Mar 2021 19:47:29
User entered 'No (N)'	System	19 Mar 2021 19:47:29

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-03-19T15:47:05-04:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '03a90216-16bc-4464-b95a-07d651aaa0f5'	System	19 Mar 2021 19:47:29
User entered 'No (N)'	System	19 Mar 2021 19:47:29

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-03-19T15:47:09-04:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '03a90216-16bc-4464-b95a-07d651aaa0f5'	System	19 Mar 2021 19:47:29
User entered 'Yes (Y)'	System	19 Mar 2021 19:47:29

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Please 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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-03-19T15:47:16-04:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '03a90216-16bc-4464-b95a-07d651aaa0f5'	System	19 Mar 2021 19:47:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Mar 2021 19:47:29

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-03-19T15:47:19-04:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '03a90216-16bc-4464-b95a-07d651aaa0f5'	System	19 Mar 2021 19:47:29
User entered '19 Mar 2021 15:47:19'	System	19 Mar 2021 19:47:29

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-03-26T11:46:04-04:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'c13edc02-54e5-4a65-b1ba-f4e632325579'	System	26 Mar 2021 15:46:12
User entered 'No (N)'	System	26 Mar 2021 15:46:12

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Have you been exposed to someone with 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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-03-26T11:46:06-04:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'c13edc02-54e5-4a65-b1ba-f4e632325579' User entered 'No (N)'	System	26 Mar 2021 15:46:12
	System	26 Mar 2021 15:46:12

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-03-26T11:46:09-04:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'c13edc02-54e5-4a65-b1ba-f4e632325579' User entered '26 Mar 2021 11:46:09'	System	26 Mar 2021 15:46:12
	System	26 Mar 2021 15:46:12

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-04-03T15:33:49-04:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '9c189544-ced5-4a34-b681-ae056678c4d' User entered 'No (N)'	System	03 Apr 2021 19:33:57

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

Have you been exposed to someone with 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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-04-03T15:33:52-04:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '9c189544-ced5-4a34-b681-ae056678c4d' User entered 'No (N)'	System	03 Apr 2021 19:33:57

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-04-03T15:33:54-04:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '9c189544-ced5-4a34-b681-ae056678c4d' User entered '03 Apr 2021 15:33:54'	System	03 Apr 2021 19:33:57
	System	03 Apr 2021 19:33:57

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-04-12T14:30:39-04:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'd916bd2f-4fca-4f63-be94-41635169c6fc' User entered 'No (N)'	System	12 Apr 2021 18:30:54
	System	12 Apr 2021 18:30:54

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

Have you been exposed to someone with 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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-04-12T14:30:42-04:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'd916bd2f-4fca-4f63-be94-41635169c6fc' User entered 'No (N)'	System	12 Apr 2021 18:30:54

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-04-12T14:30:44-04:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'd916bd2f-4fca-4f63-be94-41635169c6fc'	System	12 Apr 2021 18:30:54
User entered '12 Apr 2021 14:30:44'	System	12 Apr 2021 18:30:54

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-04-17T11:02:46-04:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '55139213-dd31-450a-a82e-8d8634fd9f93'	System	17 Apr 2021 15:03:11
User entered 'No (N)'	System	17 Apr 2021 15:03:11

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Have you been exposed to someone with 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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-04-17T11:02:49-04:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '55139213-dd31-450a-a82e-8d8634fd9f93'	System	17 Apr 2021 15:03:11
User entered 'No (N)'	System	17 Apr 2021 15:03:11

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-04-17T11:02:51-04:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '55139213-dd31-450a-a82e-8d8634fd9f93'	System	17 Apr 2021 15:03:11
User entered '17 Apr 2021 11:02:51'	System	17 Apr 2021 15:03:11

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-04-23T15:22:48-04:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '23e2b0a7-f6f1-4c22-89e1-8c3126b8508e' User entered 'No (N)'	System	23 Apr 2021 19:22:56
	System	23 Apr 2021 19:22:56

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

Have you been exposed to someone with 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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-04-23T15:22:51-04:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '23e2b0a7-f6f1-4c22-89e1-8c3126b8508e' User entered 'No (N)'	System	23 Apr 2021 19:22:56

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-04-23T15:22:53-04:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '23e2b0a7-f6f1-4c22-89e1-8c3126b8508e' User entered '23 Apr 2021 15:22:53'	System	23 Apr 2021 19:22:56
	System	23 Apr 2021 19:22:56

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-05-01T11:20:28-04:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '718e44fd-5335-4866-9a6b-2caefdabc284'	System	01 May 2021 15:20:57
User entered 'No (N)'	System	01 May 2021 15:20:57

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

Have you been exposed to someone with 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 (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-05-01T11:20:30-04:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '718e44fd-5335-4866-9a6b-2caefdabc284'	System	01 May 2021 15:20:57
User entered 'No (N)'	System	01 May 2021 15:20:57

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-05-01T11:20:33-04:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: '718e44fd-5335-4866-9a6b-2caefdabc284'	System	01 May 2021 15:20:57
User entered '01 May 2021 11:20:33'	System	01 May 2021 15:20:57

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 05:15:36

US3722215

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:35:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:15:36
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 05:15:36

US3722215

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:35:41

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)	24 Apr 2021 03:34:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-03-06T13:01:39-05:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'd3813f80-5ba9-4409-bd6a-2b27ef353596'	System	06 Mar 2021 18:04:05
User entered 'Yes (Y)'	System	06 Mar 2021 18:04:05

US3722215

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:35:41

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-03-06T13:01:45-05:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'd3813f80-5ba9-4409-bd6a-2b27ef353596'	System	06 Mar 2021 18:04:05
User entered 'No (N)'	System	06 Mar 2021 18:04:05

US3722215

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:35:41

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38FFB163-BFD1-40E6-9577-083BA5350A7A)', Time: '2021-03-06T13:01:50-05:00', User OID: 'PatientReportedOutcome (US3722215)', ODM File OID: 'd3813f80-5ba9-4409-bd6a-2b27ef353596' User entered '06 Mar 2021 13:01:50'	System	06 Mar 2021 18:04:05
	System	06 Mar 2021 18:04:05

US3722215

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:24:19
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	02 Nov 2020 20:32:27

US3722215

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:24:19
User entered '02 Nov 2020'	Taylor Wilson (b) (4)	02 Nov 2020 20:32:27

US3722215

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:24:19
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	02 Nov 2020 20:32:27

US3722215

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:24:19
User entered empty.	Taylor Wilson (b) (4)	02 Nov 2020 20:32:27

US3722215

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:24:19
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	02 Nov 2020 20:32:31

US3722215

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:39:35
User entered 'I'	System	02 Nov 2020 20:32:31

US3722215

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:30:05
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'Yes (Y)'	Marlee Smith (b) (4)	10 Dec 2020 19:28:08

US3722215

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:30:05
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered '4 Dec 2020'	Marlee Smith (b) (4)	10 Dec 2020 19:28:08

US3722215

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:30:05
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'Contact Made (CONTACT MADE)'	Marlee Smith (b) (4)	10 Dec 2020 19:28:08

US3722215

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:30:05
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered empty.	Marlee Smith (b) (4)	10 Dec 2020 19:28:08

US3722215

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:30:05
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'Yes (Y)'	Marlee Smith (b) (4)	10 Dec 2020 19:28:11

US3722215

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:30:05
User entered 'I'	System	10 Dec 2020 19:28:11

US3722215

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	04 Jan 2021 19:29:51

US3722215

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	05 Jan 2021 21:05:16
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	05 Jan 2021 21:05:16
User closed query 'The 'Date of Contact or Contact Attempt' is before the 'Date of Informed Consent'. Please review and reconcile.' (Site from System).	System	05 Jan 2021 21:05:16
User entered '04 Jan 2021' reason for change: Data Entry Error	Marlee Smith (b) (4)	05 Jan 2021 21:05:16
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	04 Jan 2021 19:29:51
User opened query 'The 'Date of Contact or Contact Attempt' is before the 'Date of Informed Consent'. Please review and reconcile.' (Site from System).	System	04 Jan 2021 19:29:51
User entered '04 Jan 2020'	Taylor Wilson (b) (4)	04 Jan 2021 19:29:51

US3722215

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	04 Jan 2021 19:29:51

US3722215

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered empty.	Taylor Wilson (b) (4)	04 Jan 2021 19:29:51

US3722215

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	04 Jan 2021 19:30:19

US3722215

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:29:12
User entered 'I'	System	04 Jan 2021 19:30:19

US3722215

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:50:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	08 Feb 2021 19:10:17

US3722215

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:50:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered '08 Feb 2021'	Taylor Wilson (b) (4)	08 Feb 2021 19:10:17

US3722215

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:50:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	08 Feb 2021 19:10:17

US3722215

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:50:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered empty.	Taylor Wilson (b) (4)	08 Feb 2021 19:10:17

US3722215

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:50:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	08 Feb 2021 19:10:22

US3722215

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:50:40
User entered 'I'	System	08 Feb 2021 19:10:22

US3722215

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'Yes (Y)'	Marlee Smith (b) (4)	22 Feb 2021 14:57:00

US3722215

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '22 Feb 2021'	(b) (4) Marlee Smith (b) (4) (b) (4)	22 Feb 2021 14:57:00

US3722215

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'Clinic (Clinic)'	Marlee Smith (b) (4)	22 Feb 2021 14:57:00

US3722215

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:35:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User entered 'VISIT4'	System	22 Feb 2021 14:57:00

US3722215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:52:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User entered 'Yes (Y)'	Marlee Smith (b) (4)	30 Mar 2021 16:07:15
	(b) (4)	

US3722215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:52:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User entered '22 Feb 2021'	Marlee Smith (b) (4)	30 Mar 2021 16:07:15
	(b) (4)	

US3722215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:52:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User entered '08:36'	Marlee Smith (b) (4)	30 Mar 2021 16:07:15
	(b) (4)	

US3722215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:52:53
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User entered '22 Feb 2021 08:36'	System	30 Mar 2021 16:07:15

US3722215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:52:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User entered '97.5' F	Marlee Smith (b) (4)	30 Mar 2021 16:07:15
	(b) (4)	

US3722215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:52:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User entered 'Oral (Oral)'	Marlee Smith (b) (4)	30 Mar 2021 16:07:15
	(b) (4)	

US3722215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:52:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User entered empty.	Marlee Smith (b) (4)	30 Mar 2021 16:07:15
	(b) (4)	

US3722215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:52:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User entered '55'	Marlee Smith (b) (4)	30 Mar 2021 16:07:15
	(b) (4)	

US3722215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:52:53
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User entered 'bpm'	System	30 Mar 2021 16:07:15

US3722215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:52:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User entered '15'	Marlee Smith (b) (4)	30 Mar 2021 16:07:15
	(b) (4)	

US3722215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:52:53
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User entered 'breaths/min'	System	30 Mar 2021 16:07:15

US3722215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:52:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User entered '119'	Marlee Smith (b) (4)	30 Mar 2021 16:07:15
	(b) (4)	

US3722215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:52:53
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User entered 'mmHg'	System	30 Mar 2021 16:07:15

US3722215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:52:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User entered '78'	Marlee Smith (b) (4)	30 Mar 2021 16:07:15
	(b) (4)	

US3722215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:52:53
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User entered 'mmHg'	System	30 Mar 2021 16:07:15

US3722215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:52:53
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36

US3722215

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:35:41

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:19
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:52:53
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36

US3722215

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:35:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'No (N)'	(b) (4) Marlee Smith (b) (4)	22 Feb 2021 14:57:18

US3722215

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:35:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered empty.	(b) (4) Marlee Smith (b) (4)	22 Feb 2021 14:57:18

US3722215

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'Yes (Y)'	Marlee Smith (b) (4)	02 Mar 2021 20:25:33

US3722215

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '22 Feb 2021'	(b) (4) Marlee Smith (b) (4)	02 Mar 2021 20:25:33
	(b) (4)	

US3722215

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered '08:37'	Marlee Smith (b) (4)	02 Mar 2021 20:25:33

US3722215

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User entered '22 Feb 2021 08:37'	System	02 Mar 2021 20:25:33

US3722215

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:25:31
User entered 'Yes (Y)'	Marlee Smith (b) (4)	22 Feb 2021 14:57:22

US3722215

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 04:02:36
User entered 'I'	System	22 Feb 2021 14:57:22

US3722215

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	05 Apr 2021 17:35:50
	(b) (4)	

US3722215

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered '05 Apr 2021'	Taylor Wilson (b) (4)	05 Apr 2021 17:35:50
	(b) (4)	

US3722215

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	05 Apr 2021 17:35:50
	(b) (4)	

US3722215

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:35:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered empty.	Taylor Wilson (b) (4)	05 Apr 2021 17:35:50
	(b) (4)	

US3722215

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	05 Apr 2021 17:35:57
	(b) (4)	

US3722215

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:35:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 17:35:57

US3722215

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

Form: Visit Date

Generated On: 10 Jun 2021 09:35:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'Yes (Y)'	Marlee Smith (b) (4)	08 Jan 2021 17:34:45

US3722215

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

Form: Visit Date

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered '8 Jan 2021'	Marlee Smith (b) (4)	08 Jan 2021 17:34:45

US3722215

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

Form: Visit Date

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'Clinic (Clinic)'	Marlee Smith (b) (4)	08 Jan 2021 17:34:45

US3722215

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

Form: Visit Date

Generated On: 10 Jun 2021 09:35:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:24:34
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 17:34:45

US3722215

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

Form: Unblinding

Generated On: 10 Jun 2021 09:35:41

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered '8 Jan 2021'	Marlee Smith (b) (4)	08 Jan 2021 17:34:55

US3722215

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

Form: Unblinding

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered '0'	(b) (4) Marlee Smith (b) (4)	22 Apr 2021 13:00:19
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 12:23:46

US3722215

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

Form: Unblinding

Generated On: 10 Jun 2021 09:35:41

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	08 Jan 2021 17:34:55

US3722215

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

Form: Unblinding

Generated On: 10 Jun 2021 09:35:41

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
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) (4), (b) (6)	23 Apr 2021 20:22:51
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 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	22 Apr 2021 13:00:22
User entered 'Amendment 6 or later (Amendment 6 or later)'	Marlee Smith (b) (4) (b) (4)	22 Apr 2021 13:00:19
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)	22 Apr 2021 10:14:59
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:23:46

US3722215

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

Form: Unblinding

Generated On: 10 Jun 2021 09:35:41

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered '8 Jan 2021'	(b) (4) Marlee Smith (b) (4) (b) (4)	08 Jan 2021 17:34:55

US3722215

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

Form: Unblinding

Generated On: 10 Jun 2021 09:35:41

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'mRNA-1273 (mRNA-1273)'	Marlee Smith (b) (4)	08 Jan 2021 17:34:55

US3722215

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

Form: Unblinding

Generated On: 10 Jun 2021 09:35:41

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 07:06:26
User entered 'mRNA-1273 (mRNA-1273)'	Marlee Smith (b) (4)	08 Jan 2021 17:34:55
	(b) (4)	

US3722215

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

Form: Unblinding

Generated On: 10 Jun 2021 09:35:41

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 07:06:26
User entered 'mRNA-1273 (mRNA-1273)'	Marlee Smith (b) (4)	08 Jan 2021 17:34:55
	(b) (4)	

US3722215

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

Form: Unblinding

Generated On: 10 Jun 2021 09:35:41

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'No (N)'	(b) (4) Marlee Smith (b) (4)	08 Jan 2021 17:34:55

US3722215

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

Form: Unblinding

Generated On: 10 Jun 2021 09:35:41

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:24:34
User entered empty.	System	08 Jan 2021 17:34:55

US3722215

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

Form: Unblinding

Generated On: 10 Jun 2021 09:35:41

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:24:34
User entered empty.	System	08 Jan 2021 17:34:55

US3722215

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	08 Jan 2021 17:35:05

US3722215

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered '8 Jan 2021'	(b) (4) Marlee Smith (b) (4) (b) (4)	08 Jan 2021 17:35:05

US3722215

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered '10:32'	(b) (4) Marlee Smith (b) (4) (b) (4)	08 Jan 2021 17:35:05

US3722215

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:35:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:24:34
User entered '8 Jan 2021 10:32'	System	08 Jan 2021 17:35:05

US3722215

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:35:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'Yes (Y)'	Marlee Smith (b) (4)	08 Jan 2021 17:35:17

US3722215

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:35:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered '8 Jan 2021'	(b) (4) Marlee Smith (b) (4)	08 Jan 2021 17:35:17

US3722215

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:35:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:24:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered '10:36'	Marlee Smith (b) (4)	08 Jan 2021 17:35:17

US3722215

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:35:41

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:24:34
User entered '8 Jan 2021 10:36'	System	08 Jan 2021 17:35:17

US3722215

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:35:41

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:04:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4)	23 Mar 2021 17:40:14
User entered 'No (N)'	Sara Poff (b) (4)	16 Feb 2021 22:12:24

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:43:28
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:04:00
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:25
User entered 'USA-US083-2021-mRNA-1273-P301000019'	System	24 Mar 2021 13:21:18
User entered 'New'	(b) (4), (b) (6)	24 Mar 2021 13:21:18

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 19:43:30
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:39:17
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Spondylolisthesis, LLT: Lumbar spondylolisthesis - version MedDRA\23.0.	Coder Import (b) (4)	21 Apr 2021 09:32:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	21 Apr 2021 09:32:00
Data point term sent to Coder	System	20 Apr 2021 16:52:01
DataPoint Un-verified.	Marlee Smith (b) (4)	20 Apr 2021 16:51:28
Coding entries removed.	(b) (4)	
	Marlee Smith (b) (4)	20 Apr 2021 16:51:28
User entered 'L3-L4 spondylolisthesis' reason for change: Data Entry Error	(b) (4)	
	Marlee Smith (b) (4)	20 Apr 2021 16:51:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 16:04:00
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Osteoarthritis of lumbar spine - version MedDRA\23.0.	Coder Import (b) (4)	24 Mar 2021 08:26:33
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Mar 2021 08:26:33
	(b) (4)	
Data point term sent to Coder	System	23 Mar 2021 17:44:16
User entered 'Worsening Osteoarthritis (Lumbar)'	Kayla Peay (b) (4)	23 Mar 2021 17:43:50
	(b) (4)	

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:43:42
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 19:43:32
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:43:38
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 19:43:35
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:35:35
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered '11 Mar 2021'	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered empty.	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:33:57
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered '14 Mar 2021'	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered empty.	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:33:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered 'Grade 3/Severe (Grade 3/Severe)'	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:43:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered '0'	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:43:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered '0'	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:43:10
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered 'l'	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:34:05
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered '11 Mar 2021'	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:34:03
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered '14 Mar 2021'	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:34:07
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:34:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered empty.	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered '0'	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered '0'	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered '0'	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered 'Not Related (NOT RELATED)'	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered 'Not Related (NOT RELATED)'	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered 'Not Applicable (NOT APPLICABLE)'	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:42:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered '0'	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered 'l'	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:42:44
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered 'l'	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:34:16
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:42:42
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:04:00
User entered empty.	Kayla Peay (b) (4) (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
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. Please leave query open until information is available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 14:54:15
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 14:54:12
User closed query 'PV Query: Please provide the additional treatment medications received during hospitalization. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 14:54:04
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. Please leave query open until information is available.' answered with 'Added relevant labs. ' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	20 Apr 2021 15:47:50
Query 'PV Query: Please provide the additional treatment medications received during hospitalization. Please leave query open until information is available.' answered with 'Updated.' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	20 Apr 2021 15:47:32
DataPoint Un-verified.	Kayla Peay (b) (4) (b) (4)	20 Apr 2021 15:47:23

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SITE REACHED OUT TO SUBJECT TO CONFIRM HEALTH CHANGE. SUBJECT RETURNED CALL ON 22 MAR 2021 AND REPORTED AN SAE OF WORSENING OSTEOARTHRITIS IN HER BACK THAT WAS LEADING TO PAIN AND DISCOMFORT, SO SHE UNDERWENT A LUMBAR FUSION ON 11 MAR 2021. SUBJECT WAS IN THE HOSPITAL FROM 11 MAR 2021 TO 14 MAR 2021. SUBJECT REPORTED BEING GIVEN MULTIPLE MEDICATIONS WHILE IN THE HOSPITAL, BUT WAS UNABLE TO RECALL DETAILS. SHE REPORTS ONLY TAKING TYLENOL AT THIS TIME. SUBJECT AGREES TO COME TO SITE TOMORROW TO COMPLETE A MEDICAL RECORDS REQUEST FORM SO ADDITIONAL DETAILS CAN BE REPORTED. SUBJECT REPORTS SHE IS RECOVERING VERY WELL AT THIS TIME. PI INFORMED OF SAE. SITE WILL FOLLOW UP ONCE RECORDS ARE AVAILABLE. Upon receipt of records, SAE was updated with a new title and medications listed in records. Site is still pending the MARS for complete record of medications. No COVID testing performed per records. 3-13-2021: Hemoglobin 10.1; Hematocrit 30.0; MCV 99.7' reason for change: Data Entry Error	Kayla Peay (b) (4)	20 Apr 2021 15:47:23
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. Please leave query open until information is available.' answered with 'No COVID testing listed in medical records. ' (Site from Safety).	Kayla Peay (b) (4)	20 Apr 2021 15:33:34

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 18:58:54
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 18:58:08
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)	19 Apr 2021 14:59:52
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 14:59:49
User opened query 'PV Query: Please provide the additional treatment medications received during hospitalization. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 17:50:25
User closed query 'PV Query: Please provide the additional treatment medications received during hospitalization. ' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 17:50:25

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Narrative](#)

Audit	User	Time (GMT)
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 'Site is still pending records. ' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	16 Apr 2021 13:48:52
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'Site is still pending records. ' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	16 Apr 2021 13:48:31
Query 'PV Query: Please provide the additional treatment medications received during hospitalization. ' answered with 'Still pending records. ' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	15 Apr 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:04:00
User opened query 'PV Query: Please provide the additional treatment medications received during hospitalization. ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 21:58:37
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)	02 Apr 2021 21:58:29
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 21:58:17

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Site reached out to subject to confirm health change. Subject returned call on 22 MAR 2021 and reported an SAE of Worsening Osteoarthritis in her back that was leading to pain and discomfort, so she underwent a lumbar fusion on 11 MAR 2021. Subject was in the hospital from 11 MAR 2021 to 14 Mar 2021. Subject reported being given multiple medications while in the hospital, but was unable to recall details. She reports only taking Tylenol at this time. Subject agrees to come to site tomorrow to complete a medical records request form so additional details can be reported. Subject reports she is recovering very well at this time. PI informed of SAE. Site will follow up once records are available.'	Kayla Peay (b) (4)	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 17:43:50

US3722215

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:35:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Mar 2021 17:43:50

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:29:18
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' answered with 'Completed' (Site from DM).	Sara Poff (b) (4) (b) (4)	14 Apr 2021 17:39:59
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 14:17:40
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:56:49

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:06
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN POTASSIUM, PRODUCTSYNONYM: COZAAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 07:38:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 07:38:21
Data point term sent to Coder	System	13 Aug 2020 14:58:09
User entered 'cozarr'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'hypertension'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered '100'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:06
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 16:56:36
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 14:57:23
User entered 'un UNK 2013'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered '0'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 14:57:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 14:57:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:35:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 14:57:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:41

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 16:15:06
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: CRESTOR - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Oct 2020 14:24:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 14:23:51
Coding entries removed.	Marlee Smith (b) (4)	21 Oct 2020 14:23:34
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: CRESTOR - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Aug 2020 14:59:21
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Aug 2020 14:59:21
	(b) (4)	
Data point term sent to Coder	System	13 Aug 2020 14:58:10
User entered 'crestor'	Kayla Peay (b) (4)	13 Aug 2020 14:57:52
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:06
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:52

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:06
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User closed query 'For consistency across pages, please consider if the indication can be updated to HYPERCHOLESTEREMIA to match term captured in medical history.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 14:04:20
Query 'For consistency across pages, please consider if the indication can be updated to HYPERCHOLESTEREMIA to match term captured in medical history.' answered with 'updated' (Site from CRA).	Marlee Smith (b) (4) (b) (4)	21 Oct 2020 14:23:42
User entered 'Hypercholesteremia' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	21 Oct 2020 14:23:34
User opened query 'For consistency across pages, please consider if the indication can be updated to HYPERCHOLESTEREMIA to match term captured in medical history.' (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 18:58:46
User entered 'hyperlipidemia'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:52

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:06
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered '20'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:52

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:06
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:52

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:06
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:52

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:06
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:52

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:41

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:06
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:52

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:06
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:52

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:06
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:52

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:06
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 16:56:45
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 14:57:52
User entered 'un Jan 2020'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:52

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:06
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered '0'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:52

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:06
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:52

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:06
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:52

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:06
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:57:52

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 14:57:52

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 14:57:52

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:35:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 14:57:52

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 16:15:04
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIDIARRHEAL MICROORGANISMS, ATC: ANTIDIARRHEAL MICROORGANISMS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Oct 2020 04:49:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Oct 2020 04:49:47
Data point term sent to Coder	System	20 Oct 2020 19:45:53
Coding entries removed.	Marlee Smith (b) (4)	20 Oct 2020 19:45:05
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 08:39:38
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 08:39:38
	(b) (4)	
Data point term sent to Coder	System	13 Aug 2020 14:59:12
User entered 'probiotic'	Kayla Peay (b) (4)	13 Aug 2020 14:58:23
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:04
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:04
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User closed query 'For consistency across pages, please consider if the indication can be updated to IRRITABLE BOWEL SYNDROME to match medical history term.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 14:04:24
Query 'For consistency across pages, please consider if the indication can be updated to IRRITABLE BOWEL SYNDROME to match medical history term.' answered with 'updated' (Site from CRA).	Marlee Smith (b) (4) (b) (4)	20 Oct 2020 19:45:11
User entered 'Irritable bowl syndrome' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	20 Oct 2020 19:45:05
User opened query 'For consistency across pages, please consider if the indication can be updated to IRRITABLE BOWEL SYNDROME to match medical history term.' (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 19:01:20
User entered 'IBS'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:04
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 13:34:40
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	15 Mar 2021 14:24:29
User entered '250' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	15 Mar 2021 14:24:24
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 20:30:46
User entered 'I'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:04
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'mg (mg)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	15 Mar 2021 14:24:24
User entered 'tablet (TABLET)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:04
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:04
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:04
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:04
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:04
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:04
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 16:56:54
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 14:58:23
User entered 'un UNK 2010'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:04
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered '0'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:04
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:04
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:04
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 14:58:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 14:58:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:35:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 14:58:23

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:02
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 15:00:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 15:00:24
Data point term sent to Coder	System	13 Aug 2020 14:59:17
User entered 'calcium'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:48

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:02
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User closed query 'Per CDM: Response is recorded as No; however, indication suggests this is being used as prophylaxis. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 13:42:32
Query 'Per CDM: Response is recorded as No; however, indication suggests this is being used as prophylaxis. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	12 Nov 2020 17:21:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	12 Nov 2020 17:21:12
User opened query 'Per CDM: Response is recorded as No; however, indication suggests this is being used as prophylaxis. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:07:16
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:48

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:02
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'supplement'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:48

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 16:15:02
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User closed query 'Per DM CLR: Please review the dose and unit recorded as these are not expected for this medication. Please review these fields and provide the actual dose instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 18:12:12
Query 'Per DM CLR: Please review the dose and unit recorded as these are not expected for this medication. Please review these fields and provide the actual dose instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4)	09 Mar 2021 15:31:36
	(b) (4)	
User entered '1000' reason for change: Data Entry Error	Marlee Smith (b) (4)	09 Mar 2021 15:30:51
	(b) (4)	
User opened query 'Per DM CLR: Please review the dose and unit recorded as these are not expected for this medication. Please review these fields and provide the actual dose instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 20:29:48
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:36:38
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Updated per request' (Site from DM).	Sara Poff (b) (4)	21 Oct 2020 18:16:36
	(b) (4)	
User entered '25' reason for change: Data Entry Error	Sara Poff (b) (4)	21 Oct 2020 18:16:07
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:41

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM). User entered '1'	(b) (4), (b) (6) Kayla Peay (b) (4) (b) (4)	28 Sep 2020 10:25:05 13 Aug 2020 14:58:48

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:02
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'mg (mg)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	09 Mar 2021 15:31:30
User entered 'tablet (TABLET)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:48

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:02
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:48

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:02
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:48

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:02
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:48

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:02
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:48

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:02
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:48

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:02
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 16:57:03
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 14:58:48
User entered 'un UNK 2005'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:48

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:02
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered '0'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:48

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:02
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:48

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:02
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:48

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:15:02
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:58:48

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 14:58:48

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 14:58:48

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:35:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 14:58:48

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:57
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:27:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:27:12
Data point term sent to Coder	System	13 Aug 2020 15:00:18
User entered 'flexeril'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:59:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:57
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:59:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:57
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'back pain'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:59:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:57
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered '10'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:59:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:57
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:59:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:57
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:59:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:57
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'twice daily (BID)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:59:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:41

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:57
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:59:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:57
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:59:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:57
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:59:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:57
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 16:57:11
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 14:59:17
User entered 'un UNK 2015'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:59:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:57
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered '0'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:59:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:57
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:59:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:57
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:59:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:57
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 14:59:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Aug 2020 14:59:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 14:59:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:35:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 14:59:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:41

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 16:14:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: CHONDROITIN;GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 17:20:33
User coded data point as Term Coded data point by	Coder Import (b) (4)	15 Oct 2020 17:20:33
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	15 Oct 2020 17:20:03
Coding entries removed.	Kayla Peay (b) (4)	15 Oct 2020 17:19:29
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: CHONDROITIN;GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 11:22:21
User coded data point as Term Coded data point by	Coder Import (b) (4)	14 Aug 2020 11:22:21
User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	13 Aug 2020 15:00:19
User entered 'glucosamine chondroitin'	Kayla Peay (b) (4)	13 Aug 2020 15:00:00
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:00

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User closed query 'For consistency across pages, please update to the indication to match the medical history term captured at screening - OSTEOARTHRITIS.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 14:04:36
Query 'For consistency across pages, please update to the indication to match the medical history term captured at screening - OSTEOARTHRITIS.' answered with 'updated' (Site from CRA).	Marlee Smith (b) (4) (b) (4)	20 Oct 2020 19:45:29
User entered 'osteoarthritis' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	15 Oct 2020 17:19:29
User opened query 'For consistency across pages, please update to the indication to match the medical history term captured at screening - OSTEOARTHRITIS.' (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 19:03:26
User entered 'OA'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:00

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User closed query 'Per DM CLR: Please review the dose and unit recorded as these are not expected for this medication. Please review these fields and provide the actual dose instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 13:36:36
Query 'Per DM CLR: Please review the dose and unit recorded as these are not expected for this medication. Please review these fields and provide the actual dose instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	15 Mar 2021 14:19:51
User entered '1500/1200' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	15 Mar 2021 14:19:46
User opened query 'Per DM CLR: Please review the dose and unit recorded as these are not expected for this medication. Please review these fields and provide the actual dose instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 20:30:16
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:36:57
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'Updated per request ' (Site from DM).	Sara Poff (b) (4) (b) (4)	21 Oct 2020 18:17:50
User entered '200' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	21 Oct 2020 18:17:36

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:41

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM). User entered '1'	(b) (4), (b) (6) Kayla Peay (b) (4) (b) (4)	28 Sep 2020 10:22:38 13 Aug 2020 15:00:00

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'mg (mg)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	15 Mar 2021 14:19:46
User entered 'tablet (TABLET)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:00

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:00

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'twice daily (BID)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:00

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:00

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:00

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:00

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 16:57:20
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 15:00:00
User entered 'un UNK 2015'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:00

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered '0'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:00

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:00

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:00

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:00

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Aug 2020 15:00:00

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 15:00:00

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:35:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 15:00:00

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL, PRODUCTSYNONYM: ESTROGEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 06:07:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 06:07:13
Data point term sent to Coder	System	13 Aug 2020 15:01:21
User entered 'estrogen patch'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:47

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:47

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'hot flashes'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:47

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered '0.25'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:47

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:47

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:47

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'other (OTHER)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:47

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:41

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'every other week'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:47

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'Transdermal (TRANSDERMAL)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:47

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:47

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 16:57:29
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 15:00:47
User entered 'un UNK 2004'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:47

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered '0'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:47

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:47

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:47

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:00:47

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 15:00:47

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 15:00:47

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:35:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 15:00:47

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:44
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:00:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:00:19
Data point term sent to Coder	System	13 Aug 2020 15:01:22
User entered 'diclofenac'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:01:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:44
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:01:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:44
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'back pain'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:01:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:44
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered '100'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:01:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:44
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'mg (mg)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:01:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:44
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:01:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:44
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'once daily (QD)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:01:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:41

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:44
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:01:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:44
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'Oral (ORAL)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:01:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:44
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:01:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:44
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 16:57:37
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 15:01:17
User entered 'un Apr 2020'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:01:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:44
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered '0'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:01:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:44
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:01:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:44
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:01:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:44
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:01:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 15:01:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 15:01:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:35:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 15:01:17

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 18:51:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 18:51:51
Data point term sent to Coder	System	23 Mar 2021 18:35:12
User entered 'Tylenol'	Marlee Smith (b) (4) (b) (4)	23 Mar 2021 18:34:31

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	23 Mar 2021 18:34:31

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'worsening osteoarthritis (lumbar)'	Marlee Smith (b) (4) (b) (4)	23 Mar 2021 18:34:31

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered '325'	Marlee Smith (b) (4) (b) (4)	23 Mar 2021 18:34:31

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'mg (mg)'	Marlee Smith (b) (4)	23 Mar 2021 18:34:31

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Marlee Smith (b) (4) (b) (4)	23 Mar 2021 18:34:31

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'as needed (PRN)'	Marlee Smith (b) (4) (b) (4)	23 Mar 2021 18:34:31

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Marlee Smith (b) (4) (b) (4)	23 Mar 2021 18:34:31

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'Oral (ORAL)'	Marlee Smith (b) (4)	23 Mar 2021 18:34:31

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered empty.	Marlee Smith (b) (4)	23 Mar 2021 18:34:31

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered '11 Mar 2021'	Marlee Smith (b) (4)	23 Mar 2021 18:34:31

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered '0'	Marlee Smith (b) (4)	23 Mar 2021 18:34:31

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 19:03:00
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	06 Apr 2021 13:16:58
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	06 Apr 2021 13:16:50
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 03:21:56
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	23 Mar 2021 18:34:31

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered '14 Mar 2021' reason for change: Data Entry Error	Marlee Smith (b) (4)	06 Apr 2021 13:16:50
User entered empty.	Marlee Smith (b) (4)	23 Mar 2021 18:34:31

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:04
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:14:06
User entered 'No (N)'	Marlee Smith (b) (4)	23 Mar 2021 18:34:31

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:04
User entered empty.	System	23 Mar 2021 18:34:31

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:04
User entered empty.	System	23 Mar 2021 18:34:31

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:35:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:04
User entered empty.	System	23 Mar 2021 18:34:31

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Apr 2021 13:30:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 13:30:53
Data point term sent to Coder	System	15 Apr 2021 13:29:40
User entered 'Botox'	Sara Poff (b) (4) (b) (4)	15 Apr 2021 13:28:48

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered 'Yes (Y)'	Sara Poff (b) (4)	15 Apr 2021 13:28:48
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered 'Cosmetic'	Sara Poff (b) (4)	15 Apr 2021 13:28:48
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered '30'	Sara Poff (b) (4)	15 Apr 2021 13:28:48
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered 'Other (OTHER)'	Sara Poff (b) (4)	15 Apr 2021 13:28:48
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered 'Units'	Sara Poff (b) (4)	15 Apr 2021 13:28:48
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered 'other (OTHER)'	Sara Poff (b) (4)	15 Apr 2021 13:28:48
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered 'Every 3 months'	Sara Poff (b) (4)	15 Apr 2021 13:28:48
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Sara Poff (b) (4) (b) (4)	15 Apr 2021 13:28:48

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered empty.	Sara Poff (b) (4)	15 Apr 2021 13:28:48
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered '10 Jan 2017'	Sara Poff (b) (4)	15 Apr 2021 13:28:48
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered '0'	Sara Poff (b) (4)	15 Apr 2021 13:28:48
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered 'Yes (Y)'	Sara Poff (b) (4)	15 Apr 2021 13:28:48
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered empty.	Sara Poff (b) (4)	15 Apr 2021 13:28:48
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered 'No (N)'	Sara Poff (b) (4)	15 Apr 2021 13:28:48
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 13:28:48

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 13:28:48

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:35:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 13:28:48

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: HYALURONIC ACID, PRODUCTSYNONYM: JUVEDERM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Apr 2021 13:32:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 13:32:21
Data point term sent to Coder	System	15 Apr 2021 13:30:41
User entered 'Juviderm'	Sara Poff (b) (4) (b) (4)	15 Apr 2021 13:30:19

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered 'Yes (Y)'	Sara Poff (b) (4)	15 Apr 2021 13:30:19
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered 'Cosmetic'	Sara Poff (b) (4)	15 Apr 2021 13:30:19
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered '1'	Sara Poff (b) (4)	15 Apr 2021 13:30:19
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered 'Other (OTHER)'	Sara Poff (b) (4)	15 Apr 2021 13:30:19
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered 'Syringe'	Sara Poff (b) (4)	15 Apr 2021 13:30:19
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered 'other (OTHER)'	Sara Poff (b) (4)	15 Apr 2021 13:30:19
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered 'Every 3 months'	Sara Poff (b) (4)	15 Apr 2021 13:30:19
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Sara Poff (b) (4) (b) (4)	15 Apr 2021 13:30:19

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered empty.	Sara Poff (b) (4)	15 Apr 2021 13:30:19
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered '10 Jan 2017'	Sara Poff (b) (4)	15 Apr 2021 13:30:19
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered '0'	Sara Poff (b) (4)	15 Apr 2021 13:30:19
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered 'Yes (Y)'	Sara Poff (b) (4)	15 Apr 2021 13:30:19
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered empty.	Sara Poff (b) (4)	15 Apr 2021 13:30:19
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered 'No (N)'	Sara Poff (b) (4)	15 Apr 2021 13:30:19
	(b) (4)	

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 13:30:19

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 13:30:19

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:35:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 13:30:19

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 16:48:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 16:48:37
Data point term sent to Coder	System	20 Apr 2021 16:47:54
User entered 'Tylenol'	Marlee Smith (b) (4)	20 Apr 2021 16:47:05

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'No (N)'	Marlee Smith (b) (4)	20 Apr 2021 16:47:05

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'l3-l4 spondylolisthesis'	Marlee Smith (b) (4)	20 Apr 2021 16:47:05

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'I'	Marlee Smith (b) (4)	20 Apr 2021 16:47:05

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'g (g)'	Marlee Smith (b) (4)	20 Apr 2021 16:47:05

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered empty.	Marlee Smith (b) (4)	20 Apr 2021 16:47:05

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'once (ONCE)'	Marlee Smith (b) (4)	20 Apr 2021 16:47:05

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered empty.	Marlee Smith (b) (4)	20 Apr 2021 16:47:05

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'Oral (ORAL)'	Marlee Smith (b) (4)	20 Apr 2021 16:47:05

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered empty.	Marlee Smith (b) (4)	20 Apr 2021 16:47:05

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered '13 Mar 2021'	Marlee Smith (b) (4)	20 Apr 2021 16:47:05

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered '0'	Marlee Smith (b) (4)	20 Apr 2021 16:47:05

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'No (N)'	Marlee Smith (b) (4)	20 Apr 2021 16:47:05

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered '13 Mar 2021'	Marlee Smith (b) (4)	20 Apr 2021 16:47:05

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:12
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'No (N)'	Marlee Smith (b) (4)	20 Apr 2021 16:47:05

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:12
User entered empty.	System	20 Apr 2021 16:47:05

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:12
User entered empty.	System	20 Apr 2021 16:47:05

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:35:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:12
User entered empty.	System	20 Apr 2021 16:47:05

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:17
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Apr 2021 08:28:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 08:28:41
Data point term sent to Coder	System	20 Apr 2021 16:48:55
User entered 'oxygen'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 16:48:04

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:17
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'No (N)'	Marlee Smith (b) (4)	20 Apr 2021 16:48:04

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:17
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'l2-l4 spondylolisthesis'	Marlee Smith (b) (4)	20 Apr 2021 16:48:04

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:17
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered '2'	Marlee Smith (b) (4)	20 Apr 2021 16:48:04

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:17
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'Other (OTHER)'	Marlee Smith (b) (4)	20 Apr 2021 16:48:04

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:17
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'liters'	Marlee Smith (b) (4)	20 Apr 2021 16:48:04

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:17
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'as needed (PRN)'	Marlee Smith (b) (4)	20 Apr 2021 16:48:04

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:17
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered empty.	Marlee Smith (b) (4)	20 Apr 2021 16:48:04

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:17
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Marlee Smith (b) (4)	20 Apr 2021 16:48:04

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:17
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered empty.	Marlee Smith (b) (4)	20 Apr 2021 16:48:04

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:17
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered '13 Mar 2021'	Marlee Smith (b) (4)	20 Apr 2021 16:48:04

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:17
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered '0'	Marlee Smith (b) (4)	20 Apr 2021 16:48:04

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:17
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'No (N)'	Marlee Smith (b) (4)	20 Apr 2021 16:48:04

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:17
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered '13 Mar 2021'	Marlee Smith (b) (4)	20 Apr 2021 16:48:04

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:17
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'No (N)'	Marlee Smith (b) (4)	20 Apr 2021 16:48:04

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:17
User entered empty.	System	20 Apr 2021 16:48:04

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:17
User entered empty.	System	20 Apr 2021 16:48:04

US3722215

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:35:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:17
User entered empty.	System	20 Apr 2021 16:48:04

US3722215

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:35:41

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:26:34
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User closed query 'Per CDM: Concomitant Procedures has data present. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 11:52:24
Query 'Per CDM: Concomitant Procedures has data present. Please review and update accordingly. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 17:44:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 17:43:59
User opened query 'Per CDM: Concomitant Procedures has data present. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 15:16:57
User entered 'No (N)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	17 Feb 2021 20:43:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	18 Nov 2020 14:45:31
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	13 Aug 2020 15:01:25

US3722215

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:35:41

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 06:29:25
User entered '11 Mar 2021' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	23 Mar 2021 18:35:33
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4) (b) (4)	23 Mar 2021 18:35:14
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4) (b) (4)	02 Feb 2021 01:59:12
Query 'Data is required. Please complete.' answered with 'Did not qualify as a procedure ' (Site from System).	Sara Poff (b) (4) (b) (4)	02 Feb 2021 01:58:27
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 01:58:04
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4) (b) (4)	02 Feb 2021 01:58:04
User entered '25 Sep 2020'	Marlee Smith (b) (4) (b) (4)	18 Nov 2020 14:45:50

US3722215

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:35:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
User entered 'L4-L5 LUMBAR INFUSION' reason for change: Data Entry Error	Kayla Peay (b) (4)	20 Apr 2021 16:02:48
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	25 Mar 2021 06:32:42
User closed query 'Per DM CLR: Please note that only procedures or non-drug therapies are to be recorded in this page. Please review the data and record in the appropriate eCRF page.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 06:29:27
User entered 'Lumbar infusion' reason for change: Data Entry Error	Marlee Smith (b) (4)	23 Mar 2021 18:35:33
	(b) (4)	
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	23 Mar 2021 18:35:14
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	02 Feb 2021 01:59:12
	(b) (4)	
Query 'Data is required. Please complete.' answered with 'Did not qualify as a procedure' (Site from System).	Sara Poff (b) (4)	02 Feb 2021 01:58:49
	(b) (4)	
Query 'Per DM CLR: Please note that only procedures or non-drug therapies are to be recorded in this page. Please review the data and record in the appropriate eCRF page.' answered with 'Did not qualify as a procedure' (Site from DM).	Sara Poff (b) (4)	02 Feb 2021 01:58:44
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 01:58:04
User entered empty; reason for change Data Entry Error	Sara Poff (b) (4)	02 Feb 2021 01:58:04
	(b) (4)	
User opened query 'Per DM CLR: Please note that only procedures or non-drug therapies are to be recorded in this page. Please review the data and record in the appropriate eCRF page.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 09:20:41
User entered 'lumbar steroid injection'	Marlee Smith (b) (4)	18 Nov 2020 14:45:50
	(b) (4)	

US3722215

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:35:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 06:29:31
User entered 'Medical History (MH)' reason for change: Data Entry Error	Marlee Smith (b) (4)	23 Mar 2021 18:35:33
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Marlee Smith (b) (4)	23 Mar 2021 18:35:14
Query 'Data is required. Please complete.' answered with 'Did not qualify as a procedure' (Site from System).	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	Sara Poff (b) (4)	02 Feb 2021 01:59:12
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'Medical History (MH)'	Sara Poff (b) (4)	02 Feb 2021 01:58:55
	(b) (4)	
	System	02 Feb 2021 01:58:04
	Sara Poff (b) (4)	02 Feb 2021 01:58:04
	(b) (4)	
	Marlee Smith (b) (4)	18 Nov 2020 14:45:50
	(b) (4)	

US3722215

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:35:41

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
	(b) (4)	
DataPoint activated with code reason code Data required.	Marlee Smith (b) (4)	23 Mar 2021 18:35:14
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	02 Feb 2021 01:59:12
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	18 Nov 2020 14:45:50
	(b) (4)	

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'USA-US083-2021-MRNA-1273-P301000019'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'Yes (Y)'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'No (N)'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'No (N)'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'Yes (Y)'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'No (N)'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'No (N)'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'No (N)'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'Luis'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'De La Cruz'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered '2 Roper Corners Cir'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'Greenville'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'SC'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered '29615'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
User entered 'US'	System	24 Mar 2021 13:21:52

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Apr 2021 14:54:50
User entered '1'	System	24 Mar 2021 13:21:52

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'USA-US083-2021-MRNA-1273-P301000019'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'Yes (Y)'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

Death

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'No (N)'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'No (N)'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'Yes (Y)'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'No (N)'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'No (N)'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'No (N)'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'Luis'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'De La Cruz'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered '2 Roper Corners Cir'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'Greenville'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'SC'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered '29615'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
User entered 'US'	System	24 Mar 2021 13:21:52

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Apr 2021 14:54:50
User entered '1'	System	24 Mar 2021 13:21:52

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:35:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
User entered '24/Mar/2021 06:21'	System	24 Mar 2021 13:21:52

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:35:41

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
User entered 'I'	(b) (4), (b) (6)	24 Mar 2021 13:21:52

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'USA-US083-2021-MRNA-1273-P301000019'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'Yes (Y)'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'No (N)'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'No (N)'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'Yes (Y)'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'No (N)'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'No (N)'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'No (N)'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'Luis'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'De La Cruz'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered '2 Roper Corners Cir'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'Greenville'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered 'SC'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:21:44
User entered '29615'	System	24 Mar 2021 13:21:18

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:05:08
User entered 'US'	System	24 Mar 2021 13:21:52

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 09:35:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Apr 2021 14:54:50
User entered '1'	System	24 Mar 2021 13:21:52

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:35:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered '21/Apr/2021 10:54'	(b) (4) System	21 Apr 2021 14:54:50

US3722215

Folder: SAE USA-US083-2021-MRNA-1273-P301000019

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:35:41

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:53:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 14:54:50