

US3742225 (Prod: University of Maryland School of Medicine)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:29:59

All time stamps listed in this document are displayed in GMT

US3742225

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 17:41:51

Generated On: 10 Jun 2021 09:29:59

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Participant ID

US3742225

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

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US3742225

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:33:40

Generated On: 10 Jun 2021 09:29:59

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

US3742225

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 17:33:40

Generated On: 10 Jun 2021 09:29:59

Date of Birth (MMM yyyy)	(b) (6) 1998
Age	22
Age Units	YEARS
Age (Derived)	22
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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 17:33:40

Generated On: 10 Jun 2021 09:29:59

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 17:33:40

Generated On: 10 Jun 2021 09:29:59

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 17:33:40

Generated On: 10 Jun 2021 09:29:59

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Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

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



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Condition	ALLERGIES ENVIRONMENTAL
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

US3742225

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Condition	ASTHMA [MILD]
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

US3742225

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Condition	ALLERGY LATEX
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Condition	POSTURAL ORTHOSTATIC TACHYCARDIA SYNDROME
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Condition	CODENE ALLERGY
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)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Condition	TEMPOROMANDIBULAR JOINT DISORDER
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:33:46

Generated On: 10 Jun 2021 09:29:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	3 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	08:12 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 08:12
Height ( <i>xxx.x</i> )	65.5 in
Weight ( <i>xxx.x</i> )	172.5 lb
BMI ( <i>xxx.x</i> )	28.32803 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:33:40

Generated On: 10 Jun 2021 09:29:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 SEP 2020

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



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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 17:33:40

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Date of assessment (dd MMM yyyy) 3 SEP 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) \_\_\_\_\_

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 17:33:40

Generated On: 10 Jun 2021 09:29:59

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	3 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:33:40

Generated On: 10 Jun 2021 09:29:59

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**Occupational Risk**

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**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 ☒

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**Specify**

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**Location and Living Circumstances Risk (check all that apply)**

**No Risk Identified** True

**Resides in Nursing Home or Assisted Living Facility** False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:33:40

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:33:46

Generated On: 10 Jun 2021 09:29:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 17:33:46

Generated On: 10 Jun 2021 09:29:59

What was the date of randomization? (dd MMM yyyy) 03 SEP 2020

What was the participant's randomization number? 111337

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 17:33:46

Generated On: 10 Jun 2021 09:29:59

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:33:46

Generated On: 10 Jun 2021 09:29:59

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 SEP 2020
Time of assessment (00:00-23:59)	08:12 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 08:12
Temperature (xxx.x)	097.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	085 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	080 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:33:46

Generated On: 10 Jun 2021 09:29:59

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)	03 SEP 2020
Time of assessment (00:00-23:59)	09:55 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 09:55
Temperature (xxx.x)	098.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	080 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 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

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:33:46

Generated On: 10 Jun 2021 09:29:59

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 17:33:46

Generated On: 10 Jun 2021 09:29:59

Was the pregnancy test performed? Yes ☐  
No ☒

Date of test (dd MMM yyyy) \_\_\_\_\_

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_

Collection time \_\_\_\_\_

Collection date and time (derived) \_\_\_\_\_

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:33:46

Generated On: 10 Jun 2021 09:29:59

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 3 SEP 2020

What was the treatment time? (00:00-23:59) 09:25 (24 HR)

Treatment Date and Time (derived) 3 SEP 2020 09:25

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:33:46

Generated On: 10 Jun 2021 09:29:59

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

Collection date (dd MMM yyyy)	3 SEP 2020
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Collection time (00:00-23:59)	08:29 (24 HR)
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Collection date and time (derived)	3 SEP 2020 08:29
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US3742225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:33:46

Generated On: 10 Jun 2021 09:29:59

Collection date (dd MMM yyyy)			3 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:33	3 SEP 2020 08:33
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:33:46

Generated On: 10 Jun 2021 09:29:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

03 SEP 2020 09:57

PC Open Date & Time

03 SEP 2020 09:45

PC Close Date & Time

03 SEP 2020 12:15



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

PC Time Stamp	03 SEP 2020 22:35
PC Open Date & Time	03 SEP 2020 13:10
PC Close Date & Time	04 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 22:07

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 23:02

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:29:59

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 21:37

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:29:59

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**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

97.2 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

07 SEP 2020 22:17

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PC Open Date & Time

07 SEP 2020 12:00

---

PC Close Date & Time

08 SEP 2020 11:59

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US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 11:12

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

10 SEP 2020 10:13

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 09:58

PC Open Date & Time

03 SEP 2020 09:45

PC Close Date & Time

03 SEP 2020 12:15



US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 22:33

PC Open Date & Time

03 SEP 2020 13:10

PC Close Date & Time

04 SEP 2020 11:59

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 22:01

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 23:01

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 21:35

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 22:17

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 11:13

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 10:12

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐



US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 09:58
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PC Open Date & Time	03 SEP 2020 09:45
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PC Close Date & Time	03 SEP 2020 12:15
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US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 22:34
PC Open Date & Time	03 SEP 2020 13:10
PC Close Date & Time	04 SEP 2020 11:59

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:29:59

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 22:01
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:29:59

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 23:02
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒



US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:29:59

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 21:36
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:29:59

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 22:16
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

59 of 2209

EAB) (1725)

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:29:59

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 11:13
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

61 of 2209

EAB) (1725)

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:29:59

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 10:13
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3742225

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:33:40

Generated On: 10 Jun 2021 09:29:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3742225

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:33:40

Generated On: 10 Jun 2021 09:29:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742225

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:33:40

Generated On: 10 Jun 2021 09:29:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742225

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:33:40

Generated On: 10 Jun 2021 09:29:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742225

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742225

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742225

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:33:47

Generated On: 10 Jun 2021 09:29:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:33:47

Generated On: 10 Jun 2021 09:29:59

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 SEP 2020
Time of assessment (00:00-23:59)	09:22 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 09:22
Temperature (xxx.x)	098.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	083 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	071 mmHg
Diastolic Blood Pressure units	MMHG

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:33:47

Generated On: 10 Jun 2021 09:29:59

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)	30 SEP 2020
Time of assessment (00:00-23:59)	10:22 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 10:22
Temperature (xxx.x)	098.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	081 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	071 mmHg
Diastolic Blood Pressure units	MMHG



US3742225

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:33:47

Generated On: 10 Jun 2021 09:29:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3742225

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 17:33:47

Generated On: 10 Jun 2021 09:29:59

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	30 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3742225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:33:47

Generated On: 10 Jun 2021 09:29:59

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 30 SEP 2020

What was the treatment time? (00:00-23:59) 09:52 (24 HR)

Treatment Date and Time (derived) 30 SEP 2020 09:52

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

US3742225

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:33:47

Generated On: 10 Jun 2021 09:29:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 SEP 2020

Collection time (00:00-23:59)

09:16 (24 HR)

Collection date and time (derived)

30 SEP 2020 09:16

US3742225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:33:47

Generated On: 10 Jun 2021 09:29:59

Collection date (dd MMM yyyy)			30 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:12	30 SEP 2020 09:12
Nasopharyngeal Swab 2	No		

US3742225

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:33:47

Generated On: 10 Jun 2021 09:29:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

98.6 °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 30 SEP 2020 10:24

PC Open Date & Time 30 SEP 2020 10:12

PC Close Date & Time 30 SEP 2020 12:42

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °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	01 OCT 2020 09:08
PC Open Date & Time	30 SEP 2020 13:37
PC Close Date & Time	01 OCT 2020 11:59



US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 10:55

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 5

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

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

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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.

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 6

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

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

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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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 10:50

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 08:19

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 10:24

PC Open Date & Time

30 SEP 2020 10:12

PC Close Date & Time

30 SEP 2020 12:42

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 09:08

PC Open Date & Time

30 SEP 2020 13:37

PC Close Date & Time

01 OCT 2020 11:59



US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 10:55

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 10:50

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 08:19

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 10:25
PC Open Date & Time	30 SEP 2020 10:12
PC Close Date & Time	30 SEP 2020 12:42



US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 09:08
PC Open Date & Time	30 SEP 2020 13:37
PC Close Date & Time	01 OCT 2020 11:59

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:29:59

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 10:55
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:29:59

Yes ☐

PC Time stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:29:59

Yes ☐

PC Time stamp

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59



US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:29:59

Yes ☐

PC Time stamp

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:29:59

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 10:50
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:29:59

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 08:19
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3742225

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:33:40

Generated On: 10 Jun 2021 09:29:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742225

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:33:40

Generated On: 10 Jun 2021 09:29:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3742225

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:33:40

Generated On: 10 Jun 2021 09:29:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742225

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:33:40

Generated On: 10 Jun 2021 09:29:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742225

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:33:40

Generated On: 10 Jun 2021 09:29:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742225

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:33:40

Generated On: 10 Jun 2021 09:29:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742225

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:33:47

Generated On: 10 Jun 2021 09:29:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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

US3742225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:33:47

Generated On: 10 Jun 2021 09:29:59

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3742225

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:33:47

Generated On: 10 Jun 2021 09:29:59

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

28 OCT 2020

---

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

---

US3742225

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:33:47

Generated On: 10 Jun 2021 09:29:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 OCT 2020

Collection time (00:00-23:59)

09:23 (24 HR)

Collection date and time (derived)

28 OCT 2020 09:23



US3742225

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:33:47

Generated On: 10 Jun 2021 09:29:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

<b>TIMEPOINT</b>	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	05 NOV 2020 11:16:31
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3742225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 00:01:38

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3742225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	17 NOV 2020 08:20:28
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 10:27:22
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 09:39:32
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 08:56:45
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

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 <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 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"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	12 DEC 2020 00:01:40
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59



US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 09:41:53

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 11:45:27

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	02 JAN 2021 10:23:22
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 JAN 2021 10:17:03

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	16 JAN 2021 09:33:43
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 08:19:37

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 11:58:57

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 10:25:13

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59



US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 08:27:51

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 09:31:19

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 14:41:29

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 10:27:51

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 MAR 2021 09:40:46
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 MAR 2021 09:55:54
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 10:01:43

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 07:50:09

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59



US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 12:28:41

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	17 APR 2021 10:17:01
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 10:33:13

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 11:36:00

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 250

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

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

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 257

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

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

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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



US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2021 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3742225

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 JUN 2021 23:59



US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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



US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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31 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 AUG 2021 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2021 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2021 23:59
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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 355

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 AUG 2021 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2021 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 SEP 2021 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 390

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 404

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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23 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 OCT 2021 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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30 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 NOV 2021 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 432

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	13 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 NOV 2021 23:59
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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 453

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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27 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 DEC 2021 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	04 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 DEC 2021 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 DEC 2021 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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



US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 JAN 2022 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 509

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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22 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JAN 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 FEB 2022 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 FEB 2022 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 FEB 2022 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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19 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 FEB 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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26 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAR 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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05 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAR 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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12 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAR 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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19 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAR 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

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 ☐

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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26 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAR 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

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 ☐

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 APR 2022 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

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

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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09 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 APR 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 APR 2022 23:59



US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 APR 2022 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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30 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 MAY 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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21 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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28 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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04 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUN 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 649

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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11 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 JUN 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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18 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 JUN 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 663
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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02 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JUL 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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09 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUL 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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16 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUL 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 JUL 2022 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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30 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 AUG 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

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

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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06 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

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

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 AUG 2022 23:59
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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 726

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 AUG 2022 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 SEP 2022 23:59

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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24 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 SEP 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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01 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 OCT 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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08 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 OCT 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

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

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 782

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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22 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 OCT 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

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29 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 NOV 2022 23:59

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US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

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

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

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

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[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

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US3742225

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:29:59

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		06 MAR 2021 10:27:59

US3742225

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3742225

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742225

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742225

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742225

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3742225

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742225

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:28:42

Generated On: 10 Jun 2021 09:29:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742225

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:28:42

Generated On: 10 Jun 2021 09:29:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742225

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:28:42

Generated On: 10 Jun 2021 09:29:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 APR 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

US3742225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 21:28:42

Generated On: 10 Jun 2021 09:29:59

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3742225

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:28:42

Generated On: 10 Jun 2021 09:29:59

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3742225

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 21:28:42

Generated On: 10 Jun 2021 09:29:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 APR 2021
Collection time (00:00-23:59)	10:26 (24 HR)
Collection date and time (derived)	6 APR 2021 10:26

US3742225

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:28:42

Generated On: 10 Jun 2021 09:29:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3742225

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

Was Contact Attempted? Yes ☐  
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3742225**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:29:59**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3742225

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

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

Visit date (dd MMM yyyy)	14 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3742225

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

Form: Unblinding

Data signed: (b) (4) 13 Apr 2021 21:42:56

Generated On: 10 Jun 2021 09:29:59

Date of updated informed consent ( <i>dd MMM yyyy</i> )	14 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	14 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3742225

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3742225

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	14 JAN 2021
Time of assessment (00:00-23:59)	10:48 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 10:48
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	093 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	069 mmHg
Diastolic Blood Pressure units	MMHG

US3742225

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	14 JAN 2021
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 11:30
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	085 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	073 mmHg
Diastolic Blood Pressure units	MMHG

US3742225

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 JAN 2021

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



US3742225

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

Form: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	14 JAN 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3742225

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 14 JAN 2021

What was the treatment time? (00:00-23:59) 10:58 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 10:58

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

US3742225

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

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

Collection date (dd MMM yyyy)	14 JAN 2021
-------------------------------	-------------

Collection time (00:00-23:59)	10:27 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	14 JAN 2021 10:27
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US3742225

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	10:32
Collection Date and Time (derived)	14 JAN 2021 10:32

US3742225

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

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742225

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742225

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

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

US3742225

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29



US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 FEB 2021
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	9 FEB 2021 10:25
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)	076 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	075 mmHg
Diastolic Blood Pressure units	MMHG

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 FEB 2021
Time of assessment (00:00-23:59)	11:11 (24 HR)
Vital Signs Date and Time (derived)	9 FEB 2021 11:11
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	078 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	076 mmHg
Diastolic Blood Pressure units	MMHG

US3742225

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 FEB 2021

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

US3742225

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	9 FEB 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3742225

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 9 FEB 2021

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

Treatment Date and Time (derived) 9 FEB 2021 10:40

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

What was the frequency of the study treatment dosing? ONCE

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

US3742225

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742225

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742225

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3742225**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:29:59**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

Was visit performed at the participant's home or at the clinic? Home ☐  
Clinic ☐

Folder OID \_\_\_\_\_

US3742225

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	
Vital Signs Date and Time (derived)	
Temperature ( <i>xxx.x</i> )	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse ( <i>xxx</i> )	
Pulse units	
Respiratory Rate ( <i>xxx</i> )	
Respiratory Rate units	
Systolic Blood Pressure ( <i>xxx</i> )	
Systolic Blood Pressure units	
Diastolic Blood Pressure ( <i>xxx</i> )	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3742225

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:28:42

Generated On: 10 Jun 2021 09:29:59

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3742225

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 21:28:42

Generated On: 10 Jun 2021 09:29:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 APR 2021
Collection time (00:00-23:59)	10:26 (24 HR)
Collection date and time (derived)	6 APR 2021 10:26

US3742225

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 17:41:51

Generated On: 10 Jun 2021 09:29:59

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3742225

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 18:09:24

Generated On: 10 Jun 2021 09:29:59

AEID	
Adverse event	CHIARI MALFORMATION TYPE 1.5
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)	15 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 18:09:24

Generated On: 10 Jun 2021 09:29:59

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

US3742225

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 18:09:24

Generated On: 10 Jun 2021 09:29:59

AEID	USA-US127-2021-MRNA-1273-P30 1000017
Adverse event	ARNOLD CHIARI SYNDROME
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)	14 APR 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)	17 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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)	14 APR 2021
Hospital Discharge Date (dd MMM yyyy)	17 APR 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 18:09:24

Generated On: 10 Jun 2021 09:29:59

Number of Days in ICU	1
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	

US3742225

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 18:09:24

Generated On: 10 Jun 2021 09:29:59

---

IN JANUARY 2020 AND WAS  
SCHEDULED TO HAVE  
SURGERY ON 14 APR 2021.  
ADMITTED TO THE HOSPITAL  
ON 14 APR 2021 WITH A PRE-OP  
DIAGNOSIS OF ARNOLD CHIARI  
SYNDROME. HAD SURGICAL  
PROCEDURE OF SUBOCCIPITAL  
DECOMPRESSION WITH  
PERICRANAL GRAFT. WAS  
ADMITTED TO THE ICU  
POST-OP DUE TO MED HX OF  
POSTURAL TACHYCARDIA AND  
EHLERS DANLOS SYNDROME.  
WAS DISCHARGED HOME ON 17  
APR 2021.

SAE IS SURGERY FOR  
CONGENITAL CHIARI  
SYNDROME THAT BECAME  
SYMPTOMATIC, PROMPTING  
HER TO EVENTUALLY DECIDE  
TO HAVE SURGERY. IT IS THE  
ELECTIVE SURGERY THAT  
QUALIFIES THIS AS AN SAE.

---

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)	1

---

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

---

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

Yes ☒

No ☐

---

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

---

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

Name of Medication DULOXETINE

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAY 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

Name of Medication MONTELEUKAST

Prophylaxis Yes ☐  
No ☒

Indication ALLERGIES ENVIRONMENTAL

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
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"/>

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

Name of Medication ZYRTEC

Prophylaxis Yes ☐  
No ☒

Indication ALLERGIES ENVIRONMENTAL

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

Name of Medication ALBUTEROL INHALER

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 180

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1999	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

Name of Medication LEVONORGESTREL KLYEENA  
IUD

Prophylaxis Yes ☒  
No ☐

Indication CONTRACEPTION

Dose per administration 19.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY FIVE YEARS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

Name of Medication DULOXETINE

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

Name of Medication CELECOXIB

Prophylaxis Yes ☐  
No ☒

Indication ARNOLD CHIARI SYNDROME

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	24 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐  
No ☒

Indication ARNOLD CHIARI SYNDROME

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐  
No ☒

Indication ARNOLD CHIARI SYNDROME

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		21 APR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐  
No ☒

Indication ARNOLD CHIARI SYNDROME

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 23 APR 2021		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

Name of Medication ZOFRAN

Prophylaxis Yes ☐  
No ☒

Indication ARNOLD CHIARI SYNDROME

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 APR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

Name of Medication TRAMADOL

Prophylaxis Yes ☐  
No ☒

Indication ARNOLD CHIARI SYNDROME

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 APR 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"/>

US3742225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 17:42:02

Generated On: 10 Jun 2021 09:29:59

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3742225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
15 FEB 2021	TEMPOROMANDIBULAR JOINT SURGERY	Medical History	
14 APR 2021	SUBOCCIPITAL DECOMPRESSION	Adverse Event	
14 APR 2021	PERICRANIAL GRAFT	Adverse Event	

US3742225

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:29:59

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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



US3742225

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:29:59

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

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

SAEID	USA-US127-2021-MRNA-1273-P301000017
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	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

SAEID	USA-US127-2021-MRNA-1273-P301000017
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	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	29/APR/2021 15:48
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

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form (2)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

SAEID	USA-US127-2021-MRNA-1273-P301000017
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	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	30/APR/2021 10:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form (3)

Data signed: (b) (4) 01 May 2021 13:52:01

Generated On: 10 Jun 2021 09:29:59

SAEID	USA-US127-2021-MRNA-1273-P301000017
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	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	30/APR/2021 11:23
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

US3742225 (Prod: University of Maryland School of Medicine)

US3742225

Form: Participant Creation

Generated On: 10 Jun 2021 09:29:59

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:17:11
User entered 'US3742225'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 11:49:22

US3742225

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:29:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:11:10
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:26:46



US3742225

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:11:10
User entered '03 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 11:49:23

US3742225

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:29:59

[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 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:11:10
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:26:46

US3742225

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:29:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered 'SCRN'	System	03 Sep 2020 13:26:46

US3742225

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:11:14
User entered (b) (6) 1998'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 11:49:24

US3742225

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:59

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:11:14
User entered '22'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:27:08

US3742225

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:59

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User entered 'YEARS'	System	03 Sep 2020 13:27:08

US3742225

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:59

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User entered '22'	System	03 Sep 2020 13:27:20

US3742225

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:59

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:11:14
User entered 'Female (F)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:27:08



US3742225

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:59

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:11:14
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:27:08

US3742225

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:59

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:11:14
User entered 'l'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:27:08

US3742225

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:59

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:11:14
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:27:08

US3742225

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:59

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:11:14
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:27:08

US3742225

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:59

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:11:14
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:27:08

US3742225

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:59

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:11:14
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:27:08

US3742225

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:11:14
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:27:08

US3742225

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:59

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:11:14
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:27:08



US3742225

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:59

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:11:14
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:27:08

US3742225

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:29:59

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:11:14
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:27:08

US3742225

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:59

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:11:38
Query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 12:54:46
User opened query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 18:57:41
User entered '3 Sep 2020'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:27:20

US3742225

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered 'Sep 2020'	System	03 Sep 2020 13:27:20

US3742225

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered '2020'	System	03 Sep 2020 13:27:20

US3742225

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:59

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:11:38
User entered 'Amendment 3 (3)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:27:20

US3742225

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:11:38
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:27:20

US3742225

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:59

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:11:38
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:27:20



US3742225

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:59

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:11:38
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:27:20

US3742225

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:59

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:11:38
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:27:20

US3742225

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:59

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:11:38
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 11:49:23

US3742225

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:29:59

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered 'I'	System	03 Sep 2020 13:27:25

US3742225

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:11:43
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:27:25

US3742225

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:29:59

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:03
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:35:46

US3742225

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:40:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:40:40
Data point term sent to Coder	System	03 Sep 2020 14:39:56
User entered 'anxiety'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:39:35

US3742225

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User entered 'UN UNK 2018'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:39:35



US3742225

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:39:35

US3742225

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:39:35

US3742225

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:39:35

US3742225

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:39:35

US3742225

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered 'Jan 2018'	System	03 Sep 2020 14:39:35

US3742225

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered '2018'	System	03 Sep 2020 14:39:35

US3742225

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered empty.	System	03 Sep 2020 14:39:35

US3742225

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered empty.	System	03 Sep 2020 14:39:35



US3742225

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:57:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:57:46
Data point term sent to Coder	System	03 Sep 2020 14:40:58
User entered 'allergies environmental'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:40:36

US3742225

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User entered 'UN UNK 1999' reason for change:	Hassan Haji (b) (4)	03 Sep 2020 14:41:36
Data Entry Error	(b) (4)	
User entered 'UN UNK 2020'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:40:36

US3742225

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:40:36

US3742225

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:40:36

US3742225

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:40:36

US3742225

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:40:36

US3742225

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered 'Jan 1999'	System	03 Sep 2020 14:41:36
User entered 'Jan 2020'	System	03 Sep 2020 14:40:36

US3742225

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:59

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered '1999'	System	03 Sep 2020 14:41:36
User entered '2020'	System	03 Sep 2020 14:40:36



US3742225

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered empty.	System	03 Sep 2020 14:40:36

US3742225

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered empty.	System	03 Sep 2020 14:40:36

US3742225

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:56:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	23 Dec 2020 16:29:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Dec 2020 16:29:41
Data point term sent to Coder	System	23 Dec 2020 16:28:44
DataPoint Un-verified.	Kaitlin Mason (b) (4)	23 Dec 2020 16:28:24
Coding entries removed.	Kaitlin Mason (b) (4)	23 Dec 2020 16:28:24
User entered 'ASTHMA [mild]' reason for change:	Kaitlin Mason (b) (4)	23 Dec 2020 16:28:24
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:01:11
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 14:42:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 14:42:47
Data point term sent to Coder	System	03 Sep 2020 14:42:00
User entered 'asthma'	Hassan Haji (b) (4)	03 Sep 2020 14:41:02

US3742225

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User entered 'UN UNK 1999' reason for change:	Hassan Haji (b) (4)	03 Sep 2020 14:42:19
Data Entry Error	(b) (4)	
User entered 'UN UNK 2020'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:41:02

US3742225

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:41:02

US3742225

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:41:02

US3742225

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:41:02

US3742225

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:41:02



US3742225

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered 'Jan 1999'	System	03 Sep 2020 14:42:19
User entered 'Jan 2020'	System	03 Sep 2020 14:41:02

US3742225

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:59

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered '1999'	System	03 Sep 2020 14:42:19
User entered '2020'	System	03 Sep 2020 14:41:02

US3742225

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered empty.	System	03 Sep 2020 14:41:02

US3742225

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered empty.	System	03 Sep 2020 14:41:02

US3742225

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Rubber sensitivity, LLT: Latex allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 15:05:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 15:05:37
Data point term sent to Coder	System	03 Sep 2020 14:43:04
User entered 'allergy latex'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:42:55

US3742225

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User entered 'UN UNK 2014'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:42:55

US3742225

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:42:55

US3742225

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:42:55



US3742225

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:42:55

US3742225

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:42:55

US3742225

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered 'Jan 2014'	System	03 Sep 2020 14:42:55

US3742225

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered '2014'	System	03 Sep 2020 14:42:55

US3742225

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered empty.	System	03 Sep 2020 14:42:55

US3742225

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered empty.	System	03 Sep 2020 14:42:55

US3742225

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Postural orthostatic tachycardia syndrome, LLT: Postural orthostatic tachycardia syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:45:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:45:48
Data point term sent to Coder	System	03 Sep 2020 14:45:09
User entered 'postural orthostatic tachycardia syndrome'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:44:12

US3742225

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User entered 'UN UNK 2011'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:44:12



US3742225

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:44:12

US3742225

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:44:12

US3742225

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:44:12

US3742225

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:11
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:44:12

US3742225

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered 'Jan 2011'	System	03 Sep 2020 14:44:12

US3742225

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered '2011'	System	03 Sep 2020 14:44:12

US3742225

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered empty.	System	03 Sep 2020 14:44:12

**US3742225**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:29:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered empty.	System	03 Sep 2020 14:44:12



US3742225

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:56:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Jan 2021 12:38:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Jan 2021 12:38:57
Data point term sent to Coder	System	22 Jan 2021 18:22:28
User entered 'CODENE ALLERGY'	Sherry McCammon (b) (4) (b) (4)	22 Jan 2021 18:21:39

US3742225

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:56:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'UN UNK 2013'	Sherry McCammon (b) (4)	22 Jan 2021 18:21:39

US3742225

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:56:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '0'	(b) (4) Sherry McCammon (b) (4) (b) (4)	22 Jan 2021 18:21:39

US3742225

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:56:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Jan 2021 18:21:39

US3742225

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:56:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered empty.	Sherry McCammon (b) (4)	22 Jan 2021 18:21:39

US3742225

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:56:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '0'	(b) (4) Sherry McCammon (b) (4) (b) (4)	22 Jan 2021 18:21:39

US3742225

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered 'Jan 2013'	System	22 Jan 2021 18:21:39

US3742225

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered '2013'	System	22 Jan 2021 18:21:39



US3742225

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered empty.	System	22 Jan 2021 18:21:39

US3742225

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered empty.	System	22 Jan 2021 18:21:39

US3742225

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:56:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Temporomandibular joint syndrome, LLT: Temporomandibular joint disorder - version MedDRA\\23.0.	Coder Import (b) (4)	22 Jan 2021 18:23:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Jan 2021 18:23:03
Data point term sent to Coder	System	22 Jan 2021 18:22:26
User entered 'TEMPOROMANDIBULAR JOINT DISORDER'	Sherry McCammon (b) (4)	22 Jan 2021 18:22:17

US3742225

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:56:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'UN UNK 2015'	Sherry McCammon (b) (4)	22 Jan 2021 18:22:17

US3742225

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:56:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '0'	(b) (4) Sherry McCammon (b) (4) (b) (4)	22 Jan 2021 18:22:17

US3742225

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:56:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Jan 2021 18:22:17

US3742225

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:56:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered empty.	(b) (4) Sherry McCammon (b) (4) (b) (4)	22 Jan 2021 18:22:17

US3742225

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:56:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '0'	(b) (4) Sherry McCammon (b) (4) (b) (4)	22 Jan 2021 18:22:17



US3742225

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered 'Jan 2015'	System	22 Jan 2021 18:22:17

US3742225

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered '2015'	System	22 Jan 2021 18:22:17

US3742225

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered empty.	System	22 Jan 2021 18:22:17

**US3742225**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:29:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered empty.	System	22 Jan 2021 18:22:17

US3742225

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:18
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:46:08

US3742225

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:18
Query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 13:20:59
User opened query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 18:58:03
User entered '3 Sep 2020'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:46:08

US3742225

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:18
User entered '08:12'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:46:08

US3742225

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered '3 Sep 2020 08:12'	System	03 Sep 2020 14:46:08



US3742225

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:18
User entered '65.5' in	Hassan Haji (b) (4)	03 Sep 2020 14:46:08
DataPoint set to visible.	(b) (4) System	03 Sep 2020 13:27:25

US3742225

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:18
User entered '172.5' lb	Hassan Haji (b) (4)	03 Sep 2020 14:46:08
DataPoint set to visible.	(b) (4) System	03 Sep 2020 13:27:25

US3742225

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered '28.32803'	System	03 Sep 2020 14:46:08
DataPoint set to visible.	System	03 Sep 2020 13:27:25

US3742225

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered 'kg/m2'	System	03 Sep 2020 14:46:08
DataPoint set to visible.	System	03 Sep 2020 13:27:25

US3742225

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:18
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:18:19
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'CORRECTED' (Site from DM).	Sherry McCammon (b) (4) (b) (4)	24 Sep 2020 15:05:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Sherry McCammon (b) (4) (b) (4)	24 Sep 2020 15:05:48
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 13:30:10
User entered '097.5' F	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:46:08

US3742225

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:18
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	24 Sep 2020 15:05:48
User entered 'Other (Other)'	(b) (4) Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:46:08

US3742225

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:18
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	24 Sep 2020 15:05:48
User entered 'temporal'	(b) (4) Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:46:08

US3742225

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Sherry McCammon (b) (4) (b) (4)	24 Sep 2020 15:05:48
User entered '085'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:46:08



US3742225

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered 'bpm'	System	03 Sep 2020 14:46:08

US3742225

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:18
User entered missing code ND - Not Done; reason for change New Information	Sherry McCammon (b) (4) (b) (4)	24 Sep 2020 15:05:48
User entered '20'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:46:08

US3742225

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered 'breaths/min'	System	03 Sep 2020 14:46:08

US3742225

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Sherry McCammon (b) (4)	24 Sep 2020 15:05:48
User entered '122'	(b) (4) Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:46:08

US3742225

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered 'mmHg'	System	03 Sep 2020 14:46:08

US3742225

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Sherry McCammon (b) (4) (b) (4)	24 Sep 2020 15:05:48
User entered '080'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:46:08

US3742225

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered 'mmHg'	System	03 Sep 2020 14:46:08

US3742225

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55



US3742225

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55

US3742225

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:24
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:48:43

US3742225

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:24
Query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 13:21:06
User opened query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 18:58:06
User entered '3 Sep 2020'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:48:43

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:29:59

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:29
Query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 13:21:08
User opened query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 18:58:12
User entered '3 Sep 2020'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:49:46

US3742225

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:29:59

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:29
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:49:46

US3742225

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:29:59

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:29
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:49:46

US3742225

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:29:59

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:29
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:49:46

US3742225

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:29
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:49:46



US3742225

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:29:59

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:29
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:49:46

US3742225

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:29:59

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:29
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:49:46

US3742225

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:29:59

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:29
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:49:46

US3742225

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:35
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:50:30

US3742225

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:35
Query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 12:52:22
User opened query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 18:58:17
User entered '3 Sep 2020'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:50:30

US3742225

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:35
User entered 'Urine (URINE)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:50:30

US3742225

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:35
User entered 'Negative (NEGATIVE)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:50:30

US3742225

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:35
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:50:30



US3742225

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:35
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:50:30

US3742225

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:35
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:50:30

**US3742225**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:29:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User entered empty.	System	03 Sep 2020 14:50:30

US3742225

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:59

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:42
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:28:11

US3742225

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:59

**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 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:42
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:28:11

US3742225

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:59

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:42
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:28:11

US3742225

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:59

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:42
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:28:11

US3742225

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:59

[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 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:42
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:28:11



US3742225

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:59

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:42
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:28:11

US3742225

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:59

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:42
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:28:11

US3742225

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:59

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:42
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:28:11

US3742225

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:59

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:42
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:28:11

US3742225

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:59

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:42
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:28:11

US3742225

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:59

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:42
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:28:11

US3742225

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:42
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:28:11

US3742225

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:28:11



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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:59

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
User entered 'I'	Hassan Haji (b) (4)	03 Sep 2020 13:28:11

US3742225

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:59

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:42
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:28:11

US3742225

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:59

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:42
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:28:11

US3742225

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:59

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:42
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:28:11

US3742225

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:59

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:42
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:28:11

US3742225

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:59

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:42
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:28:11

US3742225

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
User entered '0'	Hassan Haji (b) (4)	03 Sep 2020 13:28:11

US3742225

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:29:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:13:55
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:12:42
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:28:11



US3742225

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:29:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:18
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:53:27

US3742225

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:29:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:18
Query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 13:20:50
User opened query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 18:57:31
User entered '3 Sep 2020'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:53:27

US3742225

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:18
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:53:27

US3742225

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:29:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered 'VISIT1'	System	03 Sep 2020 14:53:27

US3742225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:23
User entered '03 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 12:59:25

US3742225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:59

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:23
User entered '111337'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 12:59:25

US3742225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:59

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:23
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 12:59:25

US3742225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:59

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
User closed query 'per CDM: asthma present on medical history, please clarify severity and update as needed' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Dec 2020 13:03:04
Query 'per CDM: asthma present on medical history, please clarify severity and update as needed' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	23 Dec 2020 16:28:07
User opened query 'per CDM: asthma present on medical history, please clarify severity and update as needed' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 18:11:31
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:13:23
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:53:49



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:59

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:23
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:53:49

US3742225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:59

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:23
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:53:49

US3742225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:59

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:23
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:53:49

US3742225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:59

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:23
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:53:49

US3742225

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:29:59

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:23
User entered 'No (N)'	Kaitlin Mason (b) (4)	21 Sep 2020 20:00:09
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 05:04:05
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:04:02

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:30
User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 14:33:50
Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 13:13:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 13:13:32
User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 12:19:36
User entered '65.5' in	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 13:13:32
User entered '172.5' lb	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:30
User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 14:33:50
Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 13:13:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 13:13:32
User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 12:19:36
User entered '65.5' in	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 13:13:32
User entered '172.5' lb	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User accepted default value 'Pre-Dose (PREDOSE)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:30
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:30
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 13:13:32
User entered '3 Sep 2020'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:30
User entered '08:12'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered '03 Sep 2020 08:12'	System	22 Sep 2020 13:13:32
User entered '3 Sep 2020 08:12'	System	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:30
User entered '097.5' F	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:30
User entered 'Other (Other)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48



US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:30
User entered 'temporal'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:30
User entered '085'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered 'bpm'	System	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:30
User entered '20'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered 'breaths/min'	System	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:30
User entered '122'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered 'mmHg'	System	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:30
User entered '080'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48



US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered 'mmHg'	System	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:30
User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 14:33:50
Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 13:13:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 13:13:32
User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 12:19:36
User entered '65.5' in	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 13:13:32
User entered '172.5' lb	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User accepted default value 'Post-Dose (POSTDOSE)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:30
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:30
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 13:13:32
User entered '3 Sep 2020'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:30
User entered '09:55'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered '03 Sep 2020 09:55'	System	22 Sep 2020 13:13:32
User entered '3 Sep 2020 09:55'	System	03 Sep 2020 14:56:48



US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:30
User entered '098.8' F reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 13:13:32
User entered '98.8' F	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:30
User entered 'Oral (Oral)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:30
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:30
User entered '080'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered 'bpm'	System	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:30
User entered '16'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered 'breaths/min'	System	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:30
User entered '121'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48



US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered 'mmHg'	System	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:30
User entered '77'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered 'mmHg'	System	03 Sep 2020 14:56:48

US3742225

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:36
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:02:34
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:57:19

US3742225

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:36
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	18 Sep 2020 13:02:34
User entered '3 Sep 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:57:19

US3742225

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:41
User closed query 'per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 20:08:05
Query 'per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.' answered with 'ENTERED IN ERROR' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 20:00:43
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 20:00:33
User opened query 'per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:04:35
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:57:46

US3742225

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:41
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 20:00:33
User entered '3 Sep 2020'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:57:46

US3742225

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:41
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 20:00:33
User entered 'Urine (URINE)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:57:46



US3742225

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:41
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 20:00:33
User entered 'Negative (NEGATIVE)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:57:46

US3742225

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:41
User closed query 'per CDM: please input yes or no in this field' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:58:31
Query 'per CDM: please input yes or no in this field' answered with 'NOT COLLECTED' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	12 Oct 2020 13:32:31
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	12 Oct 2020 13:32:27
User opened query 'per CDM: please input yes or no in this field' (Site from DM).	(b) (4), (b) (6)	11 Oct 2020 14:23:04
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 20:00:33
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:57:46

US3742225

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:57:46

US3742225

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:57:46

US3742225

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered empty.	System	03 Sep 2020 14:57:46

US3742225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 13:39:12

US3742225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:46
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 13:39:12

US3742225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:46
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 13:39:12



US3742225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 13:39:12

US3742225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:46
User entered '3 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 13:39:12

US3742225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:46
User entered '09:25'	(b) (4), (b) (6)	03 Sep 2020 13:39:12

US3742225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered '3 Sep 2020 09:25'	System	03 Sep 2020 13:39:12

US3742225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:46
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	03 Sep 2020 13:39:12

US3742225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:13:46
User entered 'ONCE'	System	03 Sep 2020 13:39:12

US3742225

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 13:39:12

US3742225

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:52
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:29:04



US3742225

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:52
User entered '3 Sep 2020'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:29:04

US3742225

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:13:52
User entered '08:29'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:29:04

US3742225

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered '3 Sep 2020 08:29'	System	03 Sep 2020 13:29:04

US3742225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:29:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:14:26
User entered '3 Sep 2020'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:29:20

US3742225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:29:20

US3742225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:14:26
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:29:20

US3742225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:14:26
User entered '08:33'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:29:20

US3742225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered '3 Sep 2020 08:33'	System	03 Sep 2020 13:29:20



US3742225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:29:20

US3742225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:14:26
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:29:20

US3742225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:14:26
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 13:29:20

US3742225

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:59

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered empty.	System	03 Sep 2020 13:29:20

US3742225

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:14:32
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:58:05

US3742225

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered '1'	System	03 Sep 2020 14:58:05

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T09:57:03', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '4e99c99e-4b91-441e-91b0-b2d1e10038e0' User entered 'Yes (Y)'	System	03 Sep 2020 13:57:16
	System	03 Sep 2020 13:57:16



US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T09:57:07', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '4e99c99e-4b91-441e-91b0-b2d1e10038e0' User entered '98.8'	System	03 Sep 2020 13:57:16
	System	03 Sep 2020 13:57:16

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T09:57:10', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '4e99c99e-4b91-441e-91b0-b2d1e10038e0' User entered 'No (N)'	System	03 Sep 2020 13:57:16
	System	03 Sep 2020 13:57:16

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T09:57:13', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '4e99c99e-4b91-441e-91b0-b2d1e10038e0' User entered '03 Sep 2020 09:57'	System	03 Sep 2020 13:57:16
	System	03 Sep 2020 13:57:16

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '03 Sep 2020 09:45'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '03 Sep 2020 12:15'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T22:35:03', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '8ab297bc-29f3-4688-8ab2-0edd0e3b0537' User entered 'Yes (Y)'	System	04 Sep 2020 02:35:15
	System	04 Sep 2020 02:35:15

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T22:35:08', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '8ab297bc-29f3-4688-8ab2-0edd0e3b0537' User entered '98.1'	System	04 Sep 2020 02:35:15
	System	04 Sep 2020 02:35:15



US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T22:35:11', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '8ab297bc-29f3-4688-8ab2-0edd0e3b0537' User entered 'No (N)'	System	04 Sep 2020 02:35:15
	System	04 Sep 2020 02:35:15

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T22:35:13', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '8ab297bc-29f3-4688-8ab2-0edd0e3b0537' User entered '03 Sep 2020 22:35'	System	04 Sep 2020 02:35:15
	System	04 Sep 2020 02:35:15

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '03 Sep 2020 13:10'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered 'Day 2'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:29:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-04T22:06:56', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '39a32385-1880-4380-83a9-720a1a3b474b' User entered 'Yes (Y)'	System	05 Sep 2020 02:07:08
	System	05 Sep 2020 02:07:08

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:29:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-04T22:06:59', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '39a32385-1880-4380-83a9-720a1a3b474b' User entered '97.4'	System	05 Sep 2020 02:07:08
	System	05 Sep 2020 02:07:08

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-04T22:07:01', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '39a32385-1880-4380-83a9-720a1a3b474b' User entered 'No (N)'	System	05 Sep 2020 02:07:08
	System	05 Sep 2020 02:07:08



US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-04T22:07:04', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '39a32385-1880-4380-83a9-720a1a3b474b' User entered '04 Sep 2020 22:07'	System	05 Sep 2020 02:07:08
	System	05 Sep 2020 02:07:08

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered 'Day 3'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:29:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-05T23:02:17', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '930a0384-a9f3-43c5-a658-483d8874553b' User entered 'Yes (Y)'	System	06 Sep 2020 03:02:49
	System	06 Sep 2020 03:02:49

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:29:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-05T23:02:41', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '930a0384-a9f3-43c5-a658-483d8874553b' User entered '96.7'	System	06 Sep 2020 03:02:49
	System	06 Sep 2020 03:02:49

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-05T23:02:44', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '930a0384-a9f3-43c5-a658-483d8874553b' User entered 'No (N)'	System	06 Sep 2020 03:02:49
	System	06 Sep 2020 03:02:49

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-05T23:02:45', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '930a0384-a9f3-43c5-a658-483d8874553b' User entered '05 Sep 2020 23:02'	System	06 Sep 2020 03:02:49
	System	06 Sep 2020 03:02:49



US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered 'Day 4'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:29:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-06T21:37:02', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '7438453b-900a-4f9d-a547-b274caf82baf' User entered 'Yes (Y)'	System	07 Sep 2020 01:37:11
	System	07 Sep 2020 01:37:11

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:29:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-06T21:37:05', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '7438453b-900a-4f9d-a547-b274caf82baf' User entered '96.5'	System	07 Sep 2020 01:37:11
	System	07 Sep 2020 01:37:11

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-06T21:37:08', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '7438453b-900a-4f9d-a547-b274caf82baf' User entered 'No (N)'	System	07 Sep 2020 01:37:11
	System	07 Sep 2020 01:37:11

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-06T21:37:10', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '7438453b-900a-4f9d-a547-b274caf82baf' User entered '06 Sep 2020 21:37'	System	07 Sep 2020 01:37:11
	System	07 Sep 2020 01:37:11

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 13:39:12



US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered 'Day 5'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:29:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-07T22:17:27', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '4dce459b-5ed8-410b-8264-45b33f9f411a' User entered 'Yes (Y)'	System	08 Sep 2020 02:17:47
	System	08 Sep 2020 02:17:47

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:29:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-07T22:17:37', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '4dce459b-5ed8-410b-8264-45b33f9f411a' User entered '97.2'	System	08 Sep 2020 02:17:47
	System	08 Sep 2020 02:17:47

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-07T22:17:40', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '4dce459b-5ed8-410b-8264-45b33f9f411a' User entered 'No (N)'	System	08 Sep 2020 02:17:47
	System	08 Sep 2020 02:17:47

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-07T22:17:43', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '4dce459b-5ed8-410b-8264-45b33f9f411a' User entered '07 Sep 2020 22:17'	System	08 Sep 2020 02:17:47
	System	08 Sep 2020 02:17:47

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 13:39:12



US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered 'Day 6'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:29:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-09T11:12:39', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '0e8d11af-d536-43b1-b419-a33e30b6a2c7' User entered 'Yes (Y)'	System	09 Sep 2020 15:12:57
	System	09 Sep 2020 15:12:57

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:29:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-09T11:12:42', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '0e8d11af-d536-43b1-b419-a33e30b6a2c7' User entered '98.8'	System	09 Sep 2020 15:12:57
	System	09 Sep 2020 15:12:57

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-09T11:12:44', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '0e8d11af-d536-43b1-b419-a33e30b6a2c7' User entered 'No (N)'	System	09 Sep 2020 15:12:57
	System	09 Sep 2020 15:12:57

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-09T11:12:53', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '0e8d11af-d536-43b1-b419-a33e30b6a2c7' User entered '09 Sep 2020 11:12'	System	09 Sep 2020 15:12:57
	System	09 Sep 2020 15:12:57

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered 'Day 7'	System	03 Sep 2020 13:39:12



US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:29:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-10T10:13:17', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '1605babf-e8c5-445c-a151-b4a87016dc38' User entered 'Yes (Y)'	System	10 Sep 2020 14:13:27
	System	10 Sep 2020 14:13:27

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:29:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-10T10:13:20', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '1605babf-e8c5-445c-a151-b4a87016dc38' User entered '98.4'	System	10 Sep 2020 14:13:27
	System	10 Sep 2020 14:13:27

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-10T10:13:23', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '1605babf-e8c5-445c-a151-b4a87016dc38' User entered 'No (N)'	System	10 Sep 2020 14:13:27
	System	10 Sep 2020 14:13:27

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-10T10:13:25', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '1605babf-e8c5-445c-a151-b4a87016dc38' User entered '10 Sep 2020 10:13'	System	10 Sep 2020 14:13:27
	System	10 Sep 2020 14:13:27

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T09:57:44', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '859736e5-ddc0-492e-b11b-21e79aa0df7b' User entered 'None (1)'	System	03 Sep 2020 13:58:02
	System	03 Sep 2020 13:58:02



US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T09:57:46', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '859736e5-ddc0-492e-b11b-21e79aa0df7b' User entered 'No (N)'	System	03 Sep 2020 13:58:02
	System	03 Sep 2020 13:58:02

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T09:57:48', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '859736e5-ddc0-492e-b11b-21e79aa0df7b' User entered 'No (N)'	System	03 Sep 2020 13:58:02
	System	03 Sep 2020 13:58:02

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T09:57:57', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '859736e5-ddc0-492e-b11b-21e79aa0df7b' User entered 'None (1)'	System	03 Sep 2020 13:58:02
	System	03 Sep 2020 13:58:02

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T09:58:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '859736e5-ddc0-492e-b11b-21e79aa0df7b' User entered '03 Sep 2020 09:58'	System	03 Sep 2020 13:58:02
	System	03 Sep 2020 13:58:02

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '03 Sep 2020 09:45'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '03 Sep 2020 12:15'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T22:33:47', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '83467605-a23c-4056-b30d-06c07e5d0476' User entered 'None (1)'	System	04 Sep 2020 02:34:01
	System	04 Sep 2020 02:34:01



US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T22:33:49', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '83467605-a23c-4056-b30d-06c07e5d0476' User entered 'No (N)'	System	04 Sep 2020 02:34:01
	System	04 Sep 2020 02:34:01

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T22:33:51', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '83467605-a23c-4056-b30d-06c07e5d0476' User entered 'No (N)'	System	04 Sep 2020 02:34:01
	System	04 Sep 2020 02:34:01

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T22:33:56', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '83467605-a23c-4056-b30d-06c07e5d0476'	System	04 Sep 2020 02:34:01
User entered 'None (1)'	System	04 Sep 2020 02:34:01

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T22:33:59', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '83467605-a23c-4056-b30d-06c07e5d0476' User entered '03 Sep 2020 22:33'	System	04 Sep 2020 02:34:01
	System	04 Sep 2020 02:34:01

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '03 Sep 2020 13:10'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered 'Day 2'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:29:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-04T22:01:19', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '7fa46eef-4032-4819-bebf-a56ca556e5af' User entered 'None (1)'	System	05 Sep 2020 02:01:33
	System	05 Sep 2020 02:01:33



US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:29:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-04T22:01:21', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '7fa46eef-4032-4819-bebf-a56ca556e5af' User entered 'No (N)'	System	05 Sep 2020 02:01:33
	System	05 Sep 2020 02:01:33

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-04T22:01:23', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '7fa46eef-4032-4819-bebf-a56ca556e5af' User entered 'No (N)'	System	05 Sep 2020 02:01:33
	System	05 Sep 2020 02:01:33

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:29:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-04T22:01:25', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '7fa46eef-4032-4819-bebf-a56ca556e5af' User entered 'None (1)'	System	05 Sep 2020 02:01:33
	System	05 Sep 2020 02:01:33

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-04T22:01:27', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '7fa46eef-4032-4819-bebf-a56ca556e5af' User entered '04 Sep 2020 22:01'	System	05 Sep 2020 02:01:33
	System	05 Sep 2020 02:01:33

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered 'Day 3'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:29:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-05T23:01:46', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '4a15c235-61ec-42f6-aaf5-e8b739da7870' User entered 'None (1)'	System	06 Sep 2020 03:01:55
	System	06 Sep 2020 03:01:55



US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:29:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-05T23:01:48', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '4a15c235-61ec-42f6-aaf5-e8b739da7870' User entered 'No (N)'	System	06 Sep 2020 03:01:55
	System	06 Sep 2020 03:01:55

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-05T23:01:50', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '4a15c235-61ec-42f6-aaf5-e8b739da7870' User entered 'No (N)'	System	06 Sep 2020 03:01:55
	System	06 Sep 2020 03:01:55

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:29:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-05T23:01:52', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '4a15c235-61ec-42f6-aaf5-e8b739da7870' User entered 'None (1)'	System	06 Sep 2020 03:01:55
	System	06 Sep 2020 03:01:55

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-05T23:01:54', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '4a15c235-61ec-42f6-aaf5-e8b739da7870' User entered '05 Sep 2020 23:01'	System	06 Sep 2020 03:01:55
	System	06 Sep 2020 03:01:55

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered 'Day 4'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:29:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-06T21:35:48', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'd356304e-5e9f-4346-b3ef-faadcd2cb15a' User entered 'None (1)'	System	07 Sep 2020 01:35:58
	System	07 Sep 2020 01:35:58



US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:29:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-06T21:35:51', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'd356304e-5e9f-4346-b3ef-faadcd2cb15a' User entered 'No (N)'	System	07 Sep 2020 01:35:58
	System	07 Sep 2020 01:35:58

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:29:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-06T21:35:52', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'd356304e-5e9f-4346-b3ef-faadcd2cb15a' User entered 'No (N)'	System	07 Sep 2020 01:35:58
	System	07 Sep 2020 01:35:58

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:29:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-06T21:35:53', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'd356304e-5e9f-4346-b3ef-faadcd2cb15a' User entered 'None (1)'	System	07 Sep 2020 01:35:58
	System	07 Sep 2020 01:35:58

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-06T21:35:56', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'd356304e-5e9f-4346-b3ef-faadcd2cb15a' User entered '06 Sep 2020 21:35'	System	07 Sep 2020 01:35:58
	System	07 Sep 2020 01:35:58

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered 'Day 5'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:29:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-07T22:16:57', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '394aa989-139b-4772-8603-048eb93a5104'	System	08 Sep 2020 02:17:08
User entered 'None (1)'	System	08 Sep 2020 02:17:08



US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:29:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-07T22:16:59', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '394aa989-139b-4772-8603-048eb93a5104' User entered 'No (N)'	System	08 Sep 2020 02:17:08
	System	08 Sep 2020 02:17:08

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:29:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-07T22:17:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '394aa989-139b-4772-8603-048eb93a5104' User entered 'No (N)'	System	08 Sep 2020 02:17:08
	System	08 Sep 2020 02:17:08

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:29:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-07T22:17:01', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '394aa989-139b-4772-8603-048eb93a5104'	System	08 Sep 2020 02:17:08
User entered 'None (1)'	System	08 Sep 2020 02:17:08

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-07T22:17:02', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '394aa989-139b-4772-8603-048eb93a5104' User entered '07 Sep 2020 22:17'	System	08 Sep 2020 02:17:08
	System	08 Sep 2020 02:17:08

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered 'Day 6'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:29:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-09T11:12:56', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'c7ba90c3-ff2d-47fa-a35e-4727a4f4e7b7'	System	09 Sep 2020 15:13:09
User entered 'None (1)'	System	09 Sep 2020 15:13:09



US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:29:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-09T11:12:59', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'c7ba90c3-ff2d-47fa-a35e-4727a4f4e7b7' User entered 'No (N)'	System	09 Sep 2020 15:13:09
	System	09 Sep 2020 15:13:09

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:29:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-09T11:13:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'c7ba90c3-ff2d-47fa-a35e-4727a4f4e7b7' User entered 'No (N)'	System	09 Sep 2020 15:13:09
	System	09 Sep 2020 15:13:09

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:29:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-09T11:13:02', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'c7ba90c3-ff2d-47fa-a35e-4727a4f4e7b7'	System	09 Sep 2020 15:13:09
User entered 'None (1)'	System	09 Sep 2020 15:13:09

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-09T11:13:06', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'c7ba90c3-ff2d-47fa-a35e-4727a4f4e7b7' User entered '09 Sep 2020 11:13'	System	09 Sep 2020 15:13:09
	System	09 Sep 2020 15:13:09

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered 'Day 7'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:29:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-10T10:12:34', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '4c98f55b-166f-4f2a-b7bb-5f6230a8fd60'	System	10 Sep 2020 14:12:45
User entered 'None (1)'	System	10 Sep 2020 14:12:45



US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:29:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-10T10:12:36', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '4c98f55b-166f-4f2a-b7bb-5f6230a8fd60' User entered 'No (N)'	System	10 Sep 2020 14:12:45
	System	10 Sep 2020 14:12:45

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:29:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-10T10:12:37', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '4c98f55b-166f-4f2a-b7bb-5f6230a8fd60' User entered 'No (N)'	System	10 Sep 2020 14:12:45
	System	10 Sep 2020 14:12:45

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:29:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-10T10:12:38', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '4c98f55b-166f-4f2a-b7bb-5f6230a8fd60'	System	10 Sep 2020 14:12:45
User entered 'None (1)'	System	10 Sep 2020 14:12:45

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-10T10:12:43', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '4c98f55b-166f-4f2a-b7bb-5f6230a8fd60' User entered '10 Sep 2020 10:12'	System	10 Sep 2020 14:12:45
	System	10 Sep 2020 14:12:45

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T09:58:03', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '25f2328a-e7cf-46ad-8f7d-73fca255eeee' User entered 'None (0)'	System	03 Sep 2020 13:58:20
	System	03 Sep 2020 13:58:20



US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T09:58:04', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '25f2328a-e7cf-46ad-8f7d-73fca255eeee' User entered 'None (0)'	System	03 Sep 2020 13:58:20
	System	03 Sep 2020 13:58:20

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T09:58:06', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '25f2328a-e7cf-46ad-8f7d-73fca255eeee' User entered 'None (0)'	System	03 Sep 2020 13:58:20
	System	03 Sep 2020 13:58:20

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T09:58:07', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '25f2328a-e7cf-46ad-8f7d-73fca255eeee' User entered 'None (0)'	System	03 Sep 2020 13:58:20
	System	03 Sep 2020 13:58:20

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T09:58:08', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '25f2328a-e7cf-46ad-8f7d-73fca255eeee' User entered 'None (0)'	System	03 Sep 2020 13:58:20
	System	03 Sep 2020 13:58:20

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T09:58:09', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '25f2328a-e7cf-46ad-8f7d-73fca255eeee' User entered 'None (0)'	System	03 Sep 2020 13:58:20
	System	03 Sep 2020 13:58:20

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T09:58:13', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '25f2328a-e7cf-46ad-8f7d-73fca255eeee' User entered 'No (N)'	System	03 Sep 2020 13:58:20
	System	03 Sep 2020 13:58:20

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T09:58:15', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '25f2328a-e7cf-46ad-8f7d-73fca255eeee' User entered '03 Sep 2020 09:58'	System	03 Sep 2020 13:58:20
	System	03 Sep 2020 13:58:20

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '03 Sep 2020 09:45'	System	03 Sep 2020 13:39:12



US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '03 Sep 2020 12:15'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T22:34:08', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'dbb1e281-9a40-4914-acf6-f4a5814a9efc' User entered 'None (0)'	System	04 Sep 2020 02:34:26
	System	04 Sep 2020 02:34:26

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T22:34:09', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'dbb1e281-9a40-4914-acf6-f4a5814a9efc' User entered 'None (0)'	System	04 Sep 2020 02:34:26
	System	04 Sep 2020 02:34:26

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T22:34:11', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'dbb1e281-9a40-4914-acf6-f4a5814a9efc' User entered 'None (0)'	System	04 Sep 2020 02:34:26
	System	04 Sep 2020 02:34:26

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T22:34:15', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'dbb1e281-9a40-4914-acf6-f4a5814a9efc' User entered 'None (0)'	System	04 Sep 2020 02:34:26
	System	04 Sep 2020 02:34:26

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T22:34:17', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'dbb1e281-9a40-4914-acf6-f4a5814a9efc' User entered 'None (0)'	System	04 Sep 2020 02:34:26
	System	04 Sep 2020 02:34:26

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T22:34:18', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'dbb1e281-9a40-4914-acf6-f4a5814a9efc' User entered 'None (0)'	System	04 Sep 2020 02:34:26
	System	04 Sep 2020 02:34:26



US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T22:34:20', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'dbb1e281-9a40-4914-acf6-f4a5814a9efc' User entered 'No (N)'	System	04 Sep 2020 02:34:26
	System	04 Sep 2020 02:34:26

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-03T22:34:22', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'dbb1e281-9a40-4914-acf6-f4a5814a9efc' User entered '03 Sep 2020 22:34'	System	04 Sep 2020 02:34:26
	System	04 Sep 2020 02:34:26

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '03 Sep 2020 13:10'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered 'Day 2'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:29:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-04T22:01:30', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'dcff1046-b2b1-4fc4-bb37-6495810342a0' User entered 'None (0)'	System	05 Sep 2020 02:01:51
	System	05 Sep 2020 02:01:51

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:29:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-04T22:01:31', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'dcff1046-b2b1-4fc4-bb37-6495810342a0' User entered 'None (0)'	System	05 Sep 2020 02:01:51
	System	05 Sep 2020 02:01:51

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:29:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-04T22:01:32', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'dcff1046-b2b1-4fc4-bb37-6495810342a0' User entered 'None (0)'	System	05 Sep 2020 02:01:51
	System	05 Sep 2020 02:01:51



US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:29:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-04T22:01:34', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'dcff1046-b2b1-4fc4-bb37-6495810342a0' User entered 'None (0)'	System	05 Sep 2020 02:01:51
	System	05 Sep 2020 02:01:51

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:29:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-04T22:01:36', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'dcff1046-b2b1-4fc4-bb37-6495810342a0' User entered 'None (0)'	System	05 Sep 2020 02:01:51
	System	05 Sep 2020 02:01:51

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:29:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-04T22:01:37', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'dcff1046-b2b1-4fc4-bb37-6495810342a0' User entered 'None (0)'	System	05 Sep 2020 02:01:51
	System	05 Sep 2020 02:01:51

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:29:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-04T22:01:40', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'dcff1046-b2b1-4fc4-bb37-6495810342a0' User entered 'No (N)'	System	05 Sep 2020 02:01:51
	System	05 Sep 2020 02:01:51

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:29:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-04T22:01:45', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'dcff1046-b2b1-4fc4-bb37-6495810342a0' User entered '04 Sep 2020 22:01'	System	05 Sep 2020 02:01:51
	System	05 Sep 2020 02:01:51

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered 'Day 3'	System	03 Sep 2020 13:39:12



US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:29:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-05T23:01:57', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'a0be4c03-1783-4b06-aeb4-fa0ff9049601' User entered 'None (0)'	System	06 Sep 2020 03:02:12
	System	06 Sep 2020 03:02:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:29:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-05T23:01:58', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'a0be4c03-1783-4b06-aeb4-fa0ff9049601' User entered 'None (0)'	System	06 Sep 2020 03:02:12
	System	06 Sep 2020 03:02:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:29:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-05T23:02:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'a0be4c03-1783-4b06-aeb4-fa0ff9049601' User entered 'None (0)'	System	06 Sep 2020 03:02:12
	System	06 Sep 2020 03:02:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:29:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-05T23:02:01', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'a0be4c03-1783-4b06-aeb4-fa0ff9049601' User entered 'None (0)'	System	06 Sep 2020 03:02:12
	System	06 Sep 2020 03:02:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:29:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-05T23:02:03', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'a0be4c03-1783-4b06-aeb4-fa0ff9049601' User entered 'None (0)'	System	06 Sep 2020 03:02:12
	System	06 Sep 2020 03:02:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:29:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-05T23:02:04', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'a0be4c03-1783-4b06-aeb4-fa0ff9049601' User entered 'None (0)'	System	06 Sep 2020 03:02:12
	System	06 Sep 2020 03:02:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:29:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-05T23:02:06', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'a0be4c03-1783-4b06-aeb4-fa0ff9049601' User entered 'No (N)'	System	06 Sep 2020 03:02:12
	System	06 Sep 2020 03:02:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:29:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-05T23:02:10', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'a0be4c03-1783-4b06-aeb4-fa0ff9049601' User entered '05 Sep 2020 23:02'	System	06 Sep 2020 03:02:12
	System	06 Sep 2020 03:02:12



US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered 'Day 4'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:29:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-06T21:35:59', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '9f61a3de-2e9e-4662-835b-ec7ee429cc92' User entered 'None (0)'	System	07 Sep 2020 01:36:13
	System	07 Sep 2020 01:36:13

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:29:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-06T21:36:02', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '9f61a3de-2e9e-4662-835b-ec7ee429cc92' User entered 'None (0)'	System	07 Sep 2020 01:36:13
	System	07 Sep 2020 01:36:13

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:29:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-06T21:36:03', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '9f61a3de-2e9e-4662-835b-ec7ee429cc92' User entered 'None (0)'	System	07 Sep 2020 01:36:13
	System	07 Sep 2020 01:36:13

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:29:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-06T21:36:05', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '9f61a3de-2e9e-4662-835b-ec7ee429cc92' User entered 'None (0)'	System	07 Sep 2020 01:36:13
	System	07 Sep 2020 01:36:13

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:29:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-06T21:36:06', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '9f61a3de-2e9e-4662-835b-ec7ee429cc92' User entered 'None (0)'	System	07 Sep 2020 01:36:13
	System	07 Sep 2020 01:36:13



US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:29:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-06T21:36:07', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '9f61a3de-2e9e-4662-835b-ec7ee429cc92' User entered 'None (0)'	System	07 Sep 2020 01:36:13
	System	07 Sep 2020 01:36:13

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:29:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-06T21:36:10', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '9f61a3de-2e9e-4662-835b-ec7ee429cc92' User entered 'No (N)'	System	07 Sep 2020 01:36:13
	System	07 Sep 2020 01:36:13

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:29:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-06T21:36:12', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '9f61a3de-2e9e-4662-835b-ec7ee429cc92'	System	07 Sep 2020 01:36:13
User entered '06 Sep 2020 21:36'	System	07 Sep 2020 01:36:13

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered 'Day 5'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:29:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-07T22:16:41', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '401ac88b-9379-448d-843f-795a38f3047d' User entered 'None (0)'	System	08 Sep 2020 02:16:57
	System	08 Sep 2020 02:16:57

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:29:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-07T22:16:43', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '401ac88b-9379-448d-843f-795a38f3047d' User entered 'None (0)'	System	08 Sep 2020 02:16:57
	System	08 Sep 2020 02:16:57



US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:29:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-07T22:16:44', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '401ac88b-9379-448d-843f-795a38f3047d' User entered 'None (0)'	System	08 Sep 2020 02:16:57
	System	08 Sep 2020 02:16:57

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:29:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-07T22:16:45', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '401ac88b-9379-448d-843f-795a38f3047d' User entered 'None (0)'	System	08 Sep 2020 02:16:57
	System	08 Sep 2020 02:16:57

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:29:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-07T22:16:46', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '401ac88b-9379-448d-843f-795a38f3047d' User entered 'None (0)'	System	08 Sep 2020 02:16:57
	System	08 Sep 2020 02:16:57

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:29:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-07T22:16:47', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '401ac88b-9379-448d-843f-795a38f3047d' User entered 'None (0)'	System	08 Sep 2020 02:16:57
	System	08 Sep 2020 02:16:57

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:29:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-07T22:16:49', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '401ac88b-9379-448d-843f-795a38f3047d' User entered 'No (N)'	System	08 Sep 2020 02:16:57
	System	08 Sep 2020 02:16:57

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:29:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-07T22:16:52', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '401ac88b-9379-448d-843f-795a38f3047d' User entered '07 Sep 2020 22:16'	System	08 Sep 2020 02:16:57
	System	08 Sep 2020 02:16:57

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 13:39:12



US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered 'Day 6'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:29:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-09T11:13:20', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'e05f1c2b-03a9-4e85-87fb-361978744861' User entered 'None (0)'	System	09 Sep 2020 15:13:41
	System	09 Sep 2020 15:13:41

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:29:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-09T11:13:22', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'e05f1c2b-03a9-4e85-87fb-361978744861' User entered 'None (0)'	System	09 Sep 2020 15:13:41
	System	09 Sep 2020 15:13:41

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:29:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-09T11:13:23', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'e05f1c2b-03a9-4e85-87fb-361978744861' User entered 'None (0)'	System	09 Sep 2020 15:13:41
	System	09 Sep 2020 15:13:41

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:29:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-09T11:13:33', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'e05f1c2b-03a9-4e85-87fb-361978744861' User entered 'None (0)'	System	09 Sep 2020 15:13:41
	System	09 Sep 2020 15:13:41

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:29:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-09T11:13:34', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'e05f1c2b-03a9-4e85-87fb-361978744861' User entered 'None (0)'	System	09 Sep 2020 15:13:41
	System	09 Sep 2020 15:13:41

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:29:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-09T11:13:35', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'e05f1c2b-03a9-4e85-87fb-361978744861' User entered 'None (0)'	System	09 Sep 2020 15:13:41
	System	09 Sep 2020 15:13:41

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:29:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-09T11:13:37', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'e05f1c2b-03a9-4e85-87fb-361978744861' User entered 'No (N)'	System	09 Sep 2020 15:13:41
	System	09 Sep 2020 15:13:41



US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:29:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-09T11:13:39', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'e05f1c2b-03a9-4e85-87fb-361978744861' User entered '09 Sep 2020 11:13'	System	09 Sep 2020 15:13:41
	System	09 Sep 2020 15:13:41

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered 'Day 7'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:29:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-10T10:12:46', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'e475a197-c439-40f3-988f-0905c18177f0' User entered 'None (0)'	System	10 Sep 2020 14:13:07
	System	10 Sep 2020 14:13:07

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:29:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-10T10:12:47', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'e475a197-c439-40f3-988f-0905c18177f0' User entered 'None (0)'	System	10 Sep 2020 14:13:07
	System	10 Sep 2020 14:13:07

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:29:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-10T10:12:48', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'e475a197-c439-40f3-988f-0905c18177f0' User entered 'None (0)'	System	10 Sep 2020 14:13:07
	System	10 Sep 2020 14:13:07

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:29:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-10T10:12:49', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'e475a197-c439-40f3-988f-0905c18177f0' User entered 'None (0)'	System	10 Sep 2020 14:13:07
	System	10 Sep 2020 14:13:07



US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:29:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-10T10:12:50', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'e475a197-c439-40f3-988f-0905c18177f0' User entered 'None (0)'	System	10 Sep 2020 14:13:07
	System	10 Sep 2020 14:13:07

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:29:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-10T10:12:59', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'e475a197-c439-40f3-988f-0905c18177f0' User entered 'None (0)'	System	10 Sep 2020 14:13:07
	System	10 Sep 2020 14:13:07

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:29:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-10T10:13:01', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'e475a197-c439-40f3-988f-0905c18177f0' User entered 'No (N)'	System	10 Sep 2020 14:13:07
	System	10 Sep 2020 14:13:07

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:29:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-10T10:13:05', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'e475a197-c439-40f3-988f-0905c18177f0' User entered '10 Sep 2020 10:13'	System	10 Sep 2020 14:13:07
	System	10 Sep 2020 14:13:07

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 13:39:12

US3742225

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 13:39:12

US3742225

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:15:09
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 14:49:00

US3742225

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:15:09
User entered '10 Sep 2020'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 14:49:00



US3742225

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:15:09
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 14:49:00

US3742225

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:15:09
User entered empty.	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 14:49:00

US3742225

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:15:13
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	15 Sep 2020 14:49:09

US3742225

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered 'I'	System	15 Sep 2020 14:49:09

US3742225

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:15:21
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:02:47

US3742225

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:15:21
User entered '17 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:02:47

US3742225

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:15:21
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:02:47

US3742225

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:15:21
User entered empty.	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:02:47



US3742225

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:15:36
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	18 Sep 2020 13:02:56

US3742225

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered 'I'	System	18 Sep 2020 13:02:56

US3742225

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:15:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 12:41:00

US3742225

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:15:47
User entered '24 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 12:41:00

US3742225

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:15:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Sep 2020 12:41:00

US3742225

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:15:47
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 12:41:00

US3742225

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:15:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 12:41:16

US3742225

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered 'I'	System	25 Sep 2020 12:41:16



US3742225

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:26
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:30:42

US3742225

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:26
User entered '30 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:30:42

US3742225

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:26
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:30:42

US3742225

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User entered 'VISIT2'	System	30 Sep 2020 14:30:42

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User accepted default value 'Pre-Dose (PREDOSE)'	Sherry McCammon (b) (4)	30 Sep 2020 14:32:44
	(b) (4)	

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:47
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:32:44

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:47
User entered '30 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:32:44

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:47
User entered '09:22'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:32:44



US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User entered '30 Sep 2020 09:22'	System	30 Sep 2020 14:32:44

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:47
User entered '098.3' F	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:32:44

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:47
User entered 'Oral (Oral)'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:32:44

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:47
User entered empty.	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:32:44

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:47
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 14:33:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).		30 Sep 2020 14:33:10
User entered '083' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:33:10
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 14:32:44
User entered empty.	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:32:44

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User entered 'bpm'	System	30 Sep 2020 14:33:10
User entered empty.	System	30 Sep 2020 14:32:44

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:47
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 14:33:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).		30 Sep 2020 14:33:10
User entered '14' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:33:10
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 14:32:44
User entered empty.	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:32:44

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User entered 'breaths/min'	System	30 Sep 2020 14:33:10
User entered empty.	System	30 Sep 2020 14:32:44



US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:47
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 14:33:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).		30 Sep 2020 14:33:10
User entered '105' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:33:10
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 14:32:44
User entered empty.	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:32:44

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User entered 'mmHg'	System	30 Sep 2020 14:33:10
User entered empty.	System	30 Sep 2020 14:32:44

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:47
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 14:33:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).		30 Sep 2020 14:33:10
User entered '071' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:33:10
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 14:32:44
User entered empty.	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:32:44

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User entered 'mmHg'	System	30 Sep 2020 14:33:10
User entered empty.	System	30 Sep 2020 14:32:44

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User accepted default value 'Post-Dose (POSTDOSE)'	Sherry McCammon (b) (4)	30 Sep 2020 14:32:44
	(b) (4)	

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:47
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:32:44

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:47
User entered '30 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:32:44

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:47
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 14:34:52
Query 'Data is required. Please provide.' answered by System data change (Site from System).		30 Sep 2020 14:34:52
User entered '10:22' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:34:52
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 14:32:44
User entered empty.	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:32:44



US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User entered '30 Sep 2020 10:22'	System	30 Sep 2020 14:34:52
User entered empty.	System	30 Sep 2020 14:32:44

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:47
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 14:34:52
Query 'Data is required. Please provide.' answered by System data change (Site from System).		30 Sep 2020 14:34:52
User entered '098.6' F reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:34:52
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 14:32:44
User entered empty.	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:32:44

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:47
User entered 'Oral (Oral)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	30 Sep 2020 14:34:52
User entered empty.	(b) (4) Sherry McCammon (b) (4)	30 Sep 2020 14:32:44
	(b) (4)	

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:47
User entered empty.	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:32:44

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:47
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 14:34:52
Query 'Data is required. Please provide.' answered by System data change (Site from System).		30 Sep 2020 14:34:52
User entered '081' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:34:52
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 14:32:44
User entered empty.	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:32:44

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User entered 'bpm'	System	30 Sep 2020 14:34:52
User entered empty.	System	30 Sep 2020 14:32:44

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:47
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 14:34:52
Query 'Data is required. Please provide.' answered by System data change (Site from System).		30 Sep 2020 14:34:52
User entered '14' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:34:52
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 14:32:44
User entered empty.	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:32:44

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User entered 'breaths/min'	System	30 Sep 2020 14:34:52
User entered empty.	System	30 Sep 2020 14:32:44



US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:47
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 14:34:52
Query 'Data is required. Please provide.' answered by System data change (Site from System).		30 Sep 2020 14:34:52
User entered '120' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:34:52
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 14:32:44
User entered empty.	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:32:44

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User entered 'mmHg'	System	30 Sep 2020 14:34:52
User entered empty.	System	30 Sep 2020 14:32:44

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:47
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 14:34:52
Query 'Data is required. Please provide.' answered by System data change (Site from System).		30 Sep 2020 14:34:52
User entered '071' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:34:52
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 14:32:44
User entered empty.	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:32:44

US3742225

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User entered 'mmHg'	System	30 Sep 2020 14:34:52
User entered empty.	System	30 Sep 2020 14:32:44

US3742225

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:57
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:31:59

US3742225

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:16:57
User entered '30 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:31:59

US3742225

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:17:03
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:31:31

US3742225

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:17:03
User entered '30 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:31:31



US3742225

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:17:03
User entered 'Urine (URINE)'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:31:31

US3742225

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:17:03
User entered 'Negative (NEGATIVE)'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:31:31

US3742225

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:17:03
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:31:31

US3742225

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:17:03
User entered empty.	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:31:31

US3742225

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:17:03
User entered empty.	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:31:31

US3742225

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User entered empty.	System	30 Sep 2020 14:31:31

US3742225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:17:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 13:55:17

US3742225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:17:35
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 13:55:17



US3742225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:17:35
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 13:55:17

US3742225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered 'MRNA-1273 OR PLACEBO'	System	30 Sep 2020 13:55:17

US3742225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:17:35
User entered '30 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 13:55:17

US3742225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:17:35
User entered '09:52'	(b) (4), (b) (6)	30 Sep 2020 13:55:17

US3742225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered '30 Sep 2020 09:52'	System	30 Sep 2020 13:55:17

US3742225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:17:35
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	30 Sep 2020 13:55:17

US3742225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:17:35
User entered 'ONCE'	System	30 Sep 2020 13:55:17

US3742225

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered 'INTRAMUSCULAR'	System	30 Sep 2020 13:55:17



US3742225

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:17:40
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:31:16

US3742225

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:17:40
User entered '30 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:31:16

US3742225

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:17:40
User entered '09:16'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:31:16

US3742225

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered '30 Sep 2020 09:16'	System	30 Sep 2020 14:31:16

US3742225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:29:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:17:46
User entered '30 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:30:56

US3742225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sherry McCammon (b) (4)	30 Sep 2020 14:30:56

US3742225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:17:46
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:30:56

US3742225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:17:46
User entered '09:12'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:30:56



US3742225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:29:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered '30 Sep 2020 09:12'	System	30 Sep 2020 14:30:56

US3742225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sherry McCammon (b) (4)	30 Sep 2020 14:30:56

US3742225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:17:46
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:30:56

US3742225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:17:46
User entered empty.	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:30:56

US3742225

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:29:59

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered empty.	System	30 Sep 2020 14:30:56

US3742225

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:17:52
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	30 Sep 2020 14:34:59

US3742225

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered '1'	System	30 Sep 2020 14:34:59

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	30 Sep 2020 13:55:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 13:55:17



US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-30T10:24:14', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '87d92736-d80b-46d1-87d6-4053bc6f6d43' User entered 'Yes (Y)'	System	30 Sep 2020 14:24:26
	System	30 Sep 2020 14:24:26

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-30T10:24:17', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '87d92736-d80b-46d1-87d6-4053bc6f6d43' User entered '98.6'	System	30 Sep 2020 14:24:26
	System	30 Sep 2020 14:24:26

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-30T10:24:19', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '87d92736-d80b-46d1-87d6-4053bc6f6d43'	System	30 Sep 2020 14:24:26
User entered 'No (N)'	System	30 Sep 2020 14:24:26

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-30T10:24:21', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '87d92736-d80b-46d1-87d6-4053bc6f6d43'	System	30 Sep 2020 14:24:26
User entered '30 Sep 2020 10:24'	System	30 Sep 2020 14:24:26

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '30 Sep 2020 10:12'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '30 Sep 2020 12:42'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	30 Sep 2020 13:55:17
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-01T09:07:53', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '9729b82e-82fc-4e3e-b74a-36cbcf22f2ae' User entered 'Yes (Y)'	System	01 Oct 2020 13:08:07
	System	01 Oct 2020 13:08:07



US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-01T09:07:58', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '9729b82e-82fc-4e3e-b74a-36cbcf22f2ae' User entered '97.8'	System	01 Oct 2020 13:08:07
	System	01 Oct 2020 13:08:07

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-01T09:08:01', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '9729b82e-82fc-4e3e-b74a-36cbcf22f2ae'	System	01 Oct 2020 13:08:07
User entered 'No (N)'	System	01 Oct 2020 13:08:07

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-01T09:08:03', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '9729b82e-82fc-4e3e-b74a-36cbcf22f2ae' User entered '01 Oct 2020 09:08'	System	01 Oct 2020 13:08:07
	System	01 Oct 2020 13:08:07

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '30 Sep 2020 13:37'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	30 Sep 2020 13:55:17
User entered 'Day 2'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:29:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-02T10:55:06', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '86537bec-046f-4061-902b-6c73197e12ce' User entered 'Yes (Y)'	System	02 Oct 2020 14:55:16
	System	02 Oct 2020 14:55:16

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:29:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-02T10:55:09', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '86537bec-046f-4061-902b-6c73197e12ce' User entered '98.7'	System	02 Oct 2020 14:55:16
	System	02 Oct 2020 14:55:16



US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:29:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-02T10:55:11', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '86537bec-046f-4061-902b-6c73197e12ce' User entered 'No (N)'	System	02 Oct 2020 14:55:16
	System	02 Oct 2020 14:55:16

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-02T10:55:12', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '86537bec-046f-4061-902b-6c73197e12ce' User entered '02 Oct 2020 10:55'	System	02 Oct 2020 14:55:16
	System	02 Oct 2020 14:55:16

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	30 Sep 2020 13:55:17
User entered 'Day 3'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:29:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:29:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:29:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08



US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:29:59

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:29:59

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	30 Sep 2020 13:55:17
User entered 'Day 4'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:29:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:29:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08



US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:29:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:29:59

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:29:59

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	30 Sep 2020 13:55:17
User entered 'Day 5'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:29:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08



US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:29:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:29:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:29:59

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:29:59

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	30 Sep 2020 13:55:17
User entered 'Day 6'	System	30 Sep 2020 13:55:17



US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:29:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-06T10:50:18', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '382b92a1-7bc3-4152-9258-357e7a583fd5' User entered 'Yes (Y)'	System	06 Oct 2020 14:50:30
	System	06 Oct 2020 14:50:30

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:29:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-06T10:50:23', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '382b92a1-7bc3-4152-9258-357e7a583fd5' User entered '98.7'	System	06 Oct 2020 14:50:30
	System	06 Oct 2020 14:50:30

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:29:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-06T10:50:25', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '382b92a1-7bc3-4152-9258-357e7a583fd5' User entered 'No (N)'	System	06 Oct 2020 14:50:30
	System	06 Oct 2020 14:50:30

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-06T10:50:27', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '382b92a1-7bc3-4152-9258-357e7a583fd5' User entered '06 Oct 2020 10:50'	System	06 Oct 2020 14:50:30
	System	06 Oct 2020 14:50:30

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	30 Sep 2020 13:55:17
User entered 'Day 7'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:29:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-07T08:18:54', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'e0dc35f5-91ff-4601-b221-e75cb0992370' User entered 'Yes (Y)'	System	07 Oct 2020 12:19:08
	System	07 Oct 2020 12:19:08



US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:29:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-07T08:19:01', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'e0dc35f5-91ff-4601-b221-e75cb0992370' User entered '98.8'	System	07 Oct 2020 12:19:08
	System	07 Oct 2020 12:19:08

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:29:59

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-07T08:19:03', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'e0dc35f5-91ff-4601-b221-e75cb0992370' User entered 'No (N)'	System	07 Oct 2020 12:19:08
	System	07 Oct 2020 12:19:08

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-07T08:19:06', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'e0dc35f5-91ff-4601-b221-e75cb0992370' User entered '07 Oct 2020 08:19'	System	07 Oct 2020 12:19:08
	System	07 Oct 2020 12:19:08

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	30 Sep 2020 13:55:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-30T10:24:34', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'de234c6e-cd7f-4e96-8a53-3883a78103e9' User entered 'None (1)'	System	30 Sep 2020 14:24:55
	System	30 Sep 2020 14:24:55

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-30T10:24:43', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'de234c6e-cd7f-4e96-8a53-3883a78103e9' User entered 'No (N)'	System	30 Sep 2020 14:24:55
	System	30 Sep 2020 14:24:55



US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-30T10:24:45', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'de234c6e-cd7f-4e96-8a53-3883a78103e9' User entered 'No (N)'	System	30 Sep 2020 14:24:55
	System	30 Sep 2020 14:24:55

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-30T10:24:51', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'de234c6e-cd7f-4e96-8a53-3883a78103e9' User entered 'None (1)'	System	30 Sep 2020 14:24:55
	System	30 Sep 2020 14:24:55

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-30T10:24:52', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'de234c6e-cd7f-4e96-8a53-3883a78103e9' User entered '30 Sep 2020 10:24'	System	30 Sep 2020 14:24:55
	System	30 Sep 2020 14:24:55

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '30 Sep 2020 10:12'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '30 Sep 2020 12:42'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	30 Sep 2020 13:55:17
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-01T09:08:06', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '45f72a62-5e45-4de2-908d-a71dcc76d5bb' User entered 'None (1)'	System	01 Oct 2020 13:08:17
	System	01 Oct 2020 13:08:17

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-01T09:08:10', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '45f72a62-5e45-4de2-908d-a71dcc76d5bb' User entered 'No (N)'	System	01 Oct 2020 13:08:17
	System	01 Oct 2020 13:08:17



US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-01T09:08:11', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '45f72a62-5e45-4de2-908d-a71dcc76d5bb' User entered 'No (N)'	System	01 Oct 2020 13:08:17
	System	01 Oct 2020 13:08:17

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-01T09:08:13', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '45f72a62-5e45-4de2-908d-a71dcc76d5bb' User entered 'None (1)'	System	01 Oct 2020 13:08:17
	System	01 Oct 2020 13:08:17

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-01T09:08:14', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '45f72a62-5e45-4de2-908d-a71dcc76d5bb' User entered '01 Oct 2020 09:08'	System	01 Oct 2020 13:08:17
	System	01 Oct 2020 13:08:17

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '30 Sep 2020 13:37'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	30 Sep 2020 13:55:17
User entered 'Day 2'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:29:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-02T10:55:14', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '4edf38b8-420a-4f37-a6bc-72eda0bea682'	System	02 Oct 2020 14:55:23
User entered 'None (1)'	System	02 Oct 2020 14:55:23

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:29:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-02T10:55:15', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '4edf38b8-420a-4f37-a6bc-72eda0bea682' User entered 'No (N)'	System	02 Oct 2020 14:55:23
	System	02 Oct 2020 14:55:23



US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:29:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-02T10:55:16', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '4edf38b8-420a-4f37-a6bc-72eda0bea682' User entered 'No (N)'	System	02 Oct 2020 14:55:23
	System	02 Oct 2020 14:55:23

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:29:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-02T10:55:17', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '4edf38b8-420a-4f37-a6bc-72eda0bea682'	System	02 Oct 2020 14:55:23
User entered 'None (1)'	System	02 Oct 2020 14:55:23

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-02T10:55:19', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '4edf38b8-420a-4f37-a6bc-72eda0bea682' User entered '02 Oct 2020 10:55'	System	02 Oct 2020 14:55:23
	System	02 Oct 2020 14:55:23

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	30 Sep 2020 13:55:17
User entered 'Day 3'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:29:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:29:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08



US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:29:59

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)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:29:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:29:59

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:29:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	30 Sep 2020 13:55:17
User entered 'Day 4'	System	30 Sep 2020 13:55:17



US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:29:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:29:59

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:29:59

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)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:29:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:29:59

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:29:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 13:55:17



US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	30 Sep 2020 13:55:17
User entered 'Day 5'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:29:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:29:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:29:59

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)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:29:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:29:59

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:29:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08



US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	30 Sep 2020 13:55:17
User entered 'Day 6'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:29:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-06T10:50:31', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '1202c5b9-9ef5-4da2-a6ae-3d1186783be0' User entered 'None (1)'	System	06 Oct 2020 14:50:39
	System	06 Oct 2020 14:50:39

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:29:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-06T10:50:33', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '1202c5b9-9ef5-4da2-a6ae-3d1186783be0' User entered 'No (N)'	System	06 Oct 2020 14:50:39
	System	06 Oct 2020 14:50:39

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:29:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-06T10:50:34', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '1202c5b9-9ef5-4da2-a6ae-3d1186783be0' User entered 'No (N)'	System	06 Oct 2020 14:50:39
	System	06 Oct 2020 14:50:39

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:29:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-06T10:50:35', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '1202c5b9-9ef5-4da2-a6ae-3d1186783be0' User entered 'None (1)'	System	06 Oct 2020 14:50:39
	System	06 Oct 2020 14:50:39



US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-06T10:50:37', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '1202c5b9-9ef5-4da2-a6ae-3d1186783be0' User entered '06 Oct 2020 10:50'	System	06 Oct 2020 14:50:39
	System	06 Oct 2020 14:50:39

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	30 Sep 2020 13:55:17
User entered 'Day 7'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:29:59

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-07T08:19:09', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '2c93fe28-d9b6-4370-9e86-ce1694fa4485' User entered 'None (1)'	System	07 Oct 2020 12:19:18
	System	07 Oct 2020 12:19:18

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:29:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-07T08:19:10', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '2c93fe28-d9b6-4370-9e86-ce1694fa4485' User entered 'No (N)'	System	07 Oct 2020 12:19:18
	System	07 Oct 2020 12:19:18

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:29:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-07T08:19:11', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '2c93fe28-d9b6-4370-9e86-ce1694fa4485' User entered 'No (N)'	System	07 Oct 2020 12:19:18
	System	07 Oct 2020 12:19:18

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:29:59

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-07T08:19:12', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '2c93fe28-d9b6-4370-9e86-ce1694fa4485' User entered 'None (1)'	System	07 Oct 2020 12:19:18
	System	07 Oct 2020 12:19:18



US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:29:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-07T08:19:14', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '2c93fe28-d9b6-4370-9e86-ce1694fa4485' User entered '07 Oct 2020 08:19'	System	07 Oct 2020 12:19:18
	System	07 Oct 2020 12:19:18

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	30 Sep 2020 13:55:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-30T10:24:55', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'b47c3ab5-aba7-4f99-af45-0625a5f0b363' User entered 'None (0)'	System	30 Sep 2020 14:25:07
	System	30 Sep 2020 14:25:07

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-30T10:24:56', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'b47c3ab5-aba7-4f99-af45-0625a5f0b363' User entered 'None (0)'	System	30 Sep 2020 14:25:07
	System	30 Sep 2020 14:25:07

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-30T10:24:57', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'b47c3ab5-aba7-4f99-af45-0625a5f0b363' User entered 'None (0)'	System	30 Sep 2020 14:25:07
	System	30 Sep 2020 14:25:07

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-30T10:24:58', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'b47c3ab5-aba7-4f99-af45-0625a5f0b363' User entered 'None (0)'	System	30 Sep 2020 14:25:07
	System	30 Sep 2020 14:25:07



US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-30T10:24:59', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'b47c3ab5-aba7-4f99-af45-0625a5f0b363' User entered 'None (0)'	System	30 Sep 2020 14:25:07
	System	30 Sep 2020 14:25:07

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-30T10:25:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'b47c3ab5-aba7-4f99-af45-0625a5f0b363' User entered 'None (0)'	System	30 Sep 2020 14:25:07
	System	30 Sep 2020 14:25:07

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-30T10:25:01', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'b47c3ab5-aba7-4f99-af45-0625a5f0b363' User entered 'No (N)'	System	30 Sep 2020 14:25:07
	System	30 Sep 2020 14:25:07

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-09-30T10:25:03', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'b47c3ab5-aba7-4f99-af45-0625a5f0b363' User entered '30 Sep 2020 10:25'	System	30 Sep 2020 14:25:07
	System	30 Sep 2020 14:25:07

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '30 Sep 2020 10:12'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '30 Sep 2020 12:42'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	30 Sep 2020 13:55:17
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-01T09:08:16', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '7567bbd9-1c23-4812-97fe-b1023481f369' User entered 'None (0)'	System	01 Oct 2020 13:08:26
	System	01 Oct 2020 13:08:26



US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-01T09:08:17', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '7567bbd9-1c23-4812-97fe-b1023481f369' User entered 'None (0)'	System	01 Oct 2020 13:08:26
	System	01 Oct 2020 13:08:26

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-01T09:08:18', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '7567bbd9-1c23-4812-97fe-b1023481f369' User entered 'None (0)'	System	01 Oct 2020 13:08:26
	System	01 Oct 2020 13:08:26

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-01T09:08:19', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '7567bbd9-1c23-4812-97fe-b1023481f369' User entered 'None (0)'	System	01 Oct 2020 13:08:26
	System	01 Oct 2020 13:08:26

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-01T09:08:20', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '7567bbd9-1c23-4812-97fe-b1023481f369' User entered 'None (0)'	System	01 Oct 2020 13:08:26
	System	01 Oct 2020 13:08:26

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-01T09:08:21', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '7567bbd9-1c23-4812-97fe-b1023481f369' User entered 'None (0)'	System	01 Oct 2020 13:08:26
	System	01 Oct 2020 13:08:26

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-01T09:08:22', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '7567bbd9-1c23-4812-97fe-b1023481f369' User entered 'No (N)'	System	01 Oct 2020 13:08:26
	System	01 Oct 2020 13:08:26

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-01T09:08:23', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '7567bbd9-1c23-4812-97fe-b1023481f369' User entered '01 Oct 2020 09:08'	System	01 Oct 2020 13:08:26
	System	01 Oct 2020 13:08:26

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '30 Sep 2020 13:37'	System	30 Sep 2020 13:55:17



US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	30 Sep 2020 13:55:17
User entered 'Day 2'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:29:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-02T10:55:21', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '675896ff-0931-4caf-99b4-3185682958ed' User entered 'None (0)'	System	02 Oct 2020 14:55:36
	System	02 Oct 2020 14:55:36

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:29:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-02T10:55:23', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '675896ff-0931-4caf-99b4-3185682958ed' User entered 'None (0)'	System	02 Oct 2020 14:55:36
	System	02 Oct 2020 14:55:36

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:29:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-02T10:55:23', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '675896ff-0931-4caf-99b4-3185682958ed' User entered 'None (0)'	System	02 Oct 2020 14:55:36
	System	02 Oct 2020 14:55:36

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:29:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-02T10:55:24', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '675896ff-0931-4caf-99b4-3185682958ed' User entered 'None (0)'	System	02 Oct 2020 14:55:36
	System	02 Oct 2020 14:55:36

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:29:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-02T10:55:25', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '675896ff-0931-4caf-99b4-3185682958ed' User entered 'None (0)'	System	02 Oct 2020 14:55:36
	System	02 Oct 2020 14:55:36

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:29:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-02T10:55:26', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '675896ff-0931-4caf-99b4-3185682958ed' User entered 'None (0)'	System	02 Oct 2020 14:55:36
	System	02 Oct 2020 14:55:36



US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:29:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-02T10:55:27', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '675896ff-0931-4caf-99b4-3185682958ed' User entered 'No (N)'	System	02 Oct 2020 14:55:36
	System	02 Oct 2020 14:55:36

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:29:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-02T10:55:29', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '675896ff-0931-4caf-99b4-3185682958ed' User entered '02 Oct 2020 10:55'	System	02 Oct 2020 14:55:36
	System	02 Oct 2020 14:55:36

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	30 Sep 2020 13:55:17
User entered 'Day 3'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:29:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:29:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:29:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08



US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:29:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:29:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:29:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:29:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:29:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	30 Sep 2020 13:55:17
User entered 'Day 4'	System	30 Sep 2020 13:55:17



US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:29:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:29:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:29:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:29:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:29:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:29:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:29:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:29:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08



US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	30 Sep 2020 13:55:17
User entered 'Day 5'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:29:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:29:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:29:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:29:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:29:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08



US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:29:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:29:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:29:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	30 Sep 2020 13:55:17
User entered 'Day 6'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:29:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-06T10:50:40', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'd17e94c6-d5c2-4a07-88fe-30059ab25b4e' User entered 'None (0)'	System	06 Oct 2020 14:50:57
	System	06 Oct 2020 14:50:57

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:29:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-06T10:50:42', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'd17e94c6-d5c2-4a07-88fe-30059ab25b4e' User entered 'None (0)'	System	06 Oct 2020 14:50:57
	System	06 Oct 2020 14:50:57



US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:29:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-06T10:50:43', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'd17e94c6-d5c2-4a07-88fe-30059ab25b4e' User entered 'None (0)'	System	06 Oct 2020 14:50:57
	System	06 Oct 2020 14:50:57

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:29:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-06T10:50:44', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'd17e94c6-d5c2-4a07-88fe-30059ab25b4e' User entered 'None (0)'	System	06 Oct 2020 14:50:57
	System	06 Oct 2020 14:50:57

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:29:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-06T10:50:46', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'd17e94c6-d5c2-4a07-88fe-30059ab25b4e' User entered 'None (0)'	System	06 Oct 2020 14:50:57
	System	06 Oct 2020 14:50:57

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:29:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-06T10:50:47', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'd17e94c6-d5c2-4a07-88fe-30059ab25b4e' User entered 'None (0)'	System	06 Oct 2020 14:50:57
	System	06 Oct 2020 14:50:57

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:29:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-06T10:50:50', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'd17e94c6-d5c2-4a07-88fe-30059ab25b4e' User entered 'No (N)'	System	06 Oct 2020 14:50:57
	System	06 Oct 2020 14:50:57

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:29:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-06T10:50:53', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'd17e94c6-d5c2-4a07-88fe-30059ab25b4e' User entered '06 Oct 2020 10:50'	System	06 Oct 2020 14:50:57
	System	06 Oct 2020 14:50:57

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 13:55:17



US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	30 Sep 2020 13:55:17
User entered 'Day 7'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:29:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-07T08:19:18', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '5ec5f608-285d-4944-aef7-267a2ea8e2b6' User entered 'None (0)'	System	07 Oct 2020 12:19:29
	System	07 Oct 2020 12:19:29

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:29:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-07T08:19:19', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '5ec5f608-285d-4944-aef7-267a2ea8e2b6' User entered 'None (0)'	System	07 Oct 2020 12:19:29
	System	07 Oct 2020 12:19:29

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:29:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-07T08:19:20', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '5ec5f608-285d-4944-aef7-267a2ea8e2b6' User entered 'None (0)'	System	07 Oct 2020 12:19:29
	System	07 Oct 2020 12:19:29

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:29:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-07T08:19:21', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '5ec5f608-285d-4944-aef7-267a2ea8e2b6' User entered 'None (0)'	System	07 Oct 2020 12:19:29
	System	07 Oct 2020 12:19:29

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:29:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-07T08:19:22', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '5ec5f608-285d-4944-aef7-267a2ea8e2b6' User entered 'None (0)'	System	07 Oct 2020 12:19:29
	System	07 Oct 2020 12:19:29

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:29:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-07T08:19:22', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '5ec5f608-285d-4944-aef7-267a2ea8e2b6' User entered 'None (0)'	System	07 Oct 2020 12:19:29
	System	07 Oct 2020 12:19:29

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:29:59

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-07T08:19:24', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '5ec5f608-285d-4944-aef7-267a2ea8e2b6' User entered 'No (N)'	System	07 Oct 2020 12:19:29
	System	07 Oct 2020 12:19:29



US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:29:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-10-07T08:19:26', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '5ec5f608-285d-4944-aef7-267a2ea8e2b6' User entered '07 Oct 2020 08:19'	System	07 Oct 2020 12:19:29
	System	07 Oct 2020 12:19:29

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:29:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 13:55:17

US3742225

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:29:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 13:55:17

US3742225

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:20:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 18:26:08

US3742225

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:20:01
User entered '7 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 18:26:08

US3742225

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:20:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	07 Oct 2020 18:26:08

US3742225

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:20:01
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:26:08

US3742225

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:20:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 18:26:21



US3742225

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered 'I'	System	07 Oct 2020 18:26:21

US3742225

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:20:21
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	14 Oct 2020 14:07:55

US3742225

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:20:21
User entered '14 Oct 2020'	Hassan Haji (b) (4) (b) (4)	14 Oct 2020 14:07:55

US3742225

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:20:21
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4) (b) (4)	14 Oct 2020 14:07:55

US3742225

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:20:21
User entered empty.	Hassan Haji (b) (4) (b) (4)	14 Oct 2020 14:07:55

US3742225

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:20:34
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	14 Oct 2020 14:10:18

US3742225

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered 'I'	System	14 Oct 2020 14:10:18

US3742225

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:41:16
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	21 Oct 2020 17:25:15



US3742225

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:41:16
User entered '21 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	21 Oct 2020 17:25:15

US3742225

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:41:16
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4) (b) (4)	21 Oct 2020 17:25:15

US3742225

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:41:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	21 Oct 2020 17:25:15

US3742225

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:41:21
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	21 Oct 2020 17:25:21

US3742225

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered 'I'	System	21 Oct 2020 17:25:21

US3742225

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:41:32
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	28 Oct 2020 13:56:29

US3742225

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:41:32
User entered '28 Oct 2020'	Hassan Haji (b) (4) (b) (4)	28 Oct 2020 13:56:29

US3742225

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:41:32
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4) (b) (4)	28 Oct 2020 13:56:29



US3742225

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User entered 'VISIT3'	System	28 Oct 2020 13:56:29

US3742225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:41:38
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	28 Oct 2020 13:56:35

US3742225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:41:38
User entered empty.	Hassan Haji (b) (4) (b) (4)	28 Oct 2020 13:56:35

US3742225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:41:38
User entered empty.	Hassan Haji (b) (4) (b) (4)	28 Oct 2020 13:56:35

US3742225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User entered empty.	System	28 Oct 2020 13:56:35

US3742225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:41:38
User entered empty.	Hassan Haji (b) (4) (b) (4)	28 Oct 2020 13:56:35

US3742225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:41:38
User entered empty.	Hassan Haji (b) (4) (b) (4)	28 Oct 2020 13:56:35

US3742225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:41:38
User entered empty.	Hassan Haji (b) (4) (b) (4)	28 Oct 2020 13:56:35



US3742225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:41:38
User entered empty.	Hassan Haji (b) (4) (b) (4)	28 Oct 2020 13:56:35

US3742225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User entered empty.	System	28 Oct 2020 13:56:35

US3742225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:41:38
User entered empty.	Hassan Haji (b) (4) (b) (4)	28 Oct 2020 13:56:35

US3742225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User entered empty.	System	28 Oct 2020 13:56:35

US3742225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:41:38
User entered empty.	Hassan Haji (b) (4) (b) (4)	28 Oct 2020 13:56:35

US3742225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User entered empty.	System	28 Oct 2020 13:56:35

US3742225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:41:38
User entered empty.	Hassan Haji (b) (4) (b) (4)	28 Oct 2020 13:56:35

US3742225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User entered empty.	System	28 Oct 2020 13:56:35



US3742225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14

US3742225

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14

US3742225

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:41:44
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	28 Oct 2020 13:56:42

US3742225

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:41:44
User entered '28 Oct 2020'	Hassan Haji (b) (4) (b) (4)	28 Oct 2020 13:56:42

US3742225

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:41:49
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	28 Oct 2020 13:57:28

US3742225

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:41:49
User entered '28 Oct 2020'	Hassan Haji (b) (4) (b) (4)	28 Oct 2020 13:57:28

US3742225

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:41:49
User entered '09:23'	Hassan Haji (b) (4) (b) (4)	28 Oct 2020 13:57:28

US3742225

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User entered '28 Oct 2020 09:23'	System	28 Oct 2020 13:57:28



US3742225

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:33:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:41:54
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	28 Oct 2020 13:57:32

US3742225

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:14
User entered 'I'	System	28 Oct 2020 13:57:32

US3742225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered 'Day 64'	System	03 Sep 2020 13:39:12

US3742225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-11-05T11:16:25', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '17f33d03-9245-46ad-8933-12b6f0cf10bc' User entered 'No (N)'	System	05 Nov 2020 16:16:33
	System	05 Nov 2020 16:16:33

US3742225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-11-05T11:16:28', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '17f33d03-9245-46ad-8933-12b6f0cf10bc'	System	05 Nov 2020 16:16:33
User entered 'No (N)'	System	05 Nov 2020 16:16:33

US3742225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-11-05T11:16:31', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '17f33d03-9245-46ad-8933-12b6f0cf10bc' User entered '05 Nov 2020 11:16:31'	System	05 Nov 2020 16:16:33
	System	05 Nov 2020 16:16:33

US3742225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered '03 Nov 2020 00:01'	System	03 Sep 2020 13:39:12

US3742225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered '07 Nov 2020 23:59'	System	03 Sep 2020 13:39:12



US3742225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered 'Day 71'	System	03 Sep 2020 13:39:12

US3742225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-11-10T00:01:31', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'ffb157d4-7226-4870-852b-c13126215b23'	System	10 Nov 2020 05:01:46
User entered 'No (N)'	System	10 Nov 2020 05:01:46

US3742225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-11-10T00:01:35', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'ffb157d4-7226-4870-852b-c13126215b23'	System	10 Nov 2020 05:01:46
User entered 'No (N)'	System	10 Nov 2020 05:01:46

US3742225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-11-10T00:01:38', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'ffb157d4-7226-4870-852b-c13126215b23' User entered '10 Nov 2020 00:01:38'	System	10 Nov 2020 05:01:46
	System	10 Nov 2020 05:01:46

US3742225

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered '10 Nov 2020 00:01'	System	03 Sep 2020 13:39:12

US3742225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered '14 Nov 2020 23:59'	System	03 Sep 2020 13:39:12

US3742225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered 'Day 78'	System	03 Sep 2020 13:39:12

US3742225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-11-17T08:20:25', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '4c77d940-e274-4a16-9a8d-96b9a6e076f8' User entered 'No (N)'	System	17 Nov 2020 13:20:33
	System	17 Nov 2020 13:20:33



US3742225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-11-17T08:20:26', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '4c77d940-e274-4a16-9a8d-96b9a6e076f8'	System	17 Nov 2020 13:20:33
User entered 'No (N)'	System	17 Nov 2020 13:20:33

US3742225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-11-17T08:20:28', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '4c77d940-e274-4a16-9a8d-96b9a6e076f8' User entered '17 Nov 2020 08:20:28'	System	17 Nov 2020 13:20:33
	System	17 Nov 2020 13:20:33

US3742225

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered '17 Nov 2020 00:01'	System	03 Sep 2020 13:39:12

US3742225

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:08
Data entry locked.	System	03 Sep 2020 13:39:12
User entered '21 Nov 2020 23:59'	System	03 Sep 2020 13:39:12

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-11-21T10:27:11', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'a78cc4d9-f79b-49d5-a041-831a564a36a4' User entered 'No (N)'	System	21 Nov 2020 15:27:27
	System	21 Nov 2020 15:27:27

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-11-21T10:27:19', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'a78cc4d9-f79b-49d5-a041-831a564a36a4' User entered 'No (N)'	System	21 Nov 2020 15:27:27

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-11-21T10:27:22', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'a78cc4d9-f79b-49d5-a041-831a564a36a4' User entered '21 Nov 2020 10:27:22'	System	21 Nov 2020 15:27:27
	System	21 Nov 2020 15:27:27



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:03:00

US3742225

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-11-28T09:39:28', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'e9795340-bcce-43bf-8ce1-b7362c941a63' User entered 'No (N)'	System	28 Nov 2020 14:39:37
	System	28 Nov 2020 14:39:37

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-11-28T09:39:30', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'e9795340-bcce-43bf-8ce1-b7362c941a63' User entered 'No (N)'	System	28 Nov 2020 14:39:37

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-11-28T09:39:32', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'e9795340-bcce-43bf-8ce1-b7362c941a63' User entered '28 Nov 2020 09:39:32'	System	28 Nov 2020 14:39:37
	System	28 Nov 2020 14:39:37

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:03:00

US3742225

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-12-05T08:56:41', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'b895b84c-d9b8-4e18-ac79-35db7a037e05'	System	05 Dec 2020 13:56:50
User entered 'No (N)'	System	05 Dec 2020 13:56:50

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-12-05T08:56:43', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'b895b84c-d9b8-4e18-ac79-35db7a037e05'	System	05 Dec 2020 13:56:50
User entered 'No (N)'	System	05 Dec 2020 13:56:50

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-12-05T08:56:45', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'b895b84c-d9b8-4e18-ac79-35db7a037e05' User entered '05 Dec 2020 08:56:45'	System	05 Dec 2020 13:56:50
	System	05 Dec 2020 13:56:50

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-12-12T00:01:15', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '746960b6-88d2-4e40-9123-d72c0b26eac5' User entered 'Yes (Y)'	System	12 Dec 2020 05:02:13
	System	12 Dec 2020 05:02:13



US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-12-12T00:01:18', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '746960b6-88d2-4e40-9123-d72c0b26eac5' User entered 'Yes (Y)'	System	12 Dec 2020 05:02:13
	System	12 Dec 2020 05:02:13

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-12-12T00:01:27', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '746960b6-88d2-4e40-9123-d72c0b26eac5'	System	12 Dec 2020 05:02:13
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Dec 2020 05:02:13

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-12-12T00:01:30', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '746960b6-88d2-4e40-9123-d72c0b26eac5' User entered 'No (N)'	System	12 Dec 2020 05:02:13
	System	12 Dec 2020 05:02:13

US3742225

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-12-12T00:01:33', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '746960b6-88d2-4e40-9123-d72c0b26eac5' User entered 'No (N)'	System	12 Dec 2020 05:02:13
	System	12 Dec 2020 05:02:13

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-12-12T00:01:40', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '746960b6-88d2-4e40-9123-d72c0b26eac5' User entered '12 Dec 2020 00:01:40'	System	12 Dec 2020 05:02:13
	System	12 Dec 2020 05:02:13

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-12-19T09:41:48', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '0f90fbb3-bb29-42dd-8845-d48733014eef' User entered 'No (N)'	System	19 Dec 2020 14:41:56
	System	19 Dec 2020 14:41:56

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-12-19T09:41:50', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '0f90fbb3-bb29-42dd-8845-d48733014eef' User entered 'No (N)'	System	19 Dec 2020 14:41:56
	System	19 Dec 2020 14:41:56

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-12-19T09:41:53', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '0f90fbb3-bb29-42dd-8845-d48733014eef' User entered '19 Dec 2020 09:41:53'	System	19 Dec 2020 14:41:56
	System	19 Dec 2020 14:41:56

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:03:00

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-12-26T11:45:22', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '7f0a6f91-a19e-4a4f-be99-4d213841f0ae' User entered 'No (N)'	System	26 Dec 2020 16:45:29
	System	26 Dec 2020 16:45:29

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-12-26T11:45:25', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '7f0a6f91-a19e-4a4f-be99-4d213841f0ae' User entered 'No (N)'	System	26 Dec 2020 16:45:29



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2020-12-26T11:45:27', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '7f0a6f91-a19e-4a4f-be99-4d213841f0ae' User entered '26 Dec 2020 11:45:27'	System	26 Dec 2020 16:45:29
	System	26 Dec 2020 16:45:29

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-01-02T10:23:17', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '802ae5ae-f747-4193-a950-d05981ef0518' User entered 'No (N)'	System	02 Jan 2021 15:23:26
	System	02 Jan 2021 15:23:26

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-01-02T10:23:20', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '802ae5ae-f747-4193-a950-d05981ef0518' User entered 'No (N)'	System	02 Jan 2021 15:23:26
	System	02 Jan 2021 15:23:26

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-01-02T10:23:22', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '802ae5ae-f747-4193-a950-d05981ef0518' User entered '02 Jan 2021 10:23:22'	System	02 Jan 2021 15:23:26
	System	02 Jan 2021 15:23:26

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-01-09T10:17:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'c4a80485-00ac-4fbc-8e30-87a85e184839' User entered 'No (N)'	System	09 Jan 2021 15:17:06
	System	09 Jan 2021 15:17:06

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-01-09T10:17:01', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'c4a80485-00ac-4fbc-8e30-87a85e184839' User entered 'No (N)'	System	09 Jan 2021 15:17:06
	System	09 Jan 2021 15:17:06

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-01-09T10:17:03', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'c4a80485-00ac-4fbc-8e30-87a85e184839' User entered '09 Jan 2021 10:17:03'	System	09 Jan 2021 15:17:06
	System	09 Jan 2021 15:17:06

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:03:00



US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-01-16T09:33:31', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'eff912cd-570b-4b8b-a84e-2291f2f58518' User entered 'Yes (Y)'	System	16 Jan 2021 14:33:48
	System	16 Jan 2021 14:33:48

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-01-16T09:33:34', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'eff912cd-570b-4b8b-a84e-2291f2f58518'	System	16 Jan 2021 14:33:48
User entered 'No (N)'	System	16 Jan 2021 14:33:48

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-01-16T09:33:37', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'eff912cd-570b-4b8b-a84e-2291f2f58518' User entered 'No (N)'	System	16 Jan 2021 14:33:48
	System	16 Jan 2021 14:33:48

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-01-16T09:33:41', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'eff912cd-570b-4b8b-a84e-2291f2f58518' User entered 'No (N)'	System	16 Jan 2021 14:33:48
	System	16 Jan 2021 14:33:48

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-01-16T09:33:43', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'eff912cd-570b-4b8b-a84e-2291f2f58518' User entered '16 Jan 2021 09:33:43'	System	16 Jan 2021 14:33:48
	System	16 Jan 2021 14:33:48

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-01-23T08:19:33', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '498cecbf-fc08-4f84-b668-d045d4d07e0b' User entered 'No (N)'	System	23 Jan 2021 13:19:40
	System	23 Jan 2021 13:19:40

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-01-23T08:19:34', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '498cecbf-fc08-4f84-b668-d045d4d07e0b' User entered 'No (N)'	System	23 Jan 2021 13:19:40

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-01-23T08:19:37', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '498cecbf-fc08-4f84-b668-d045d4d07e0b' User entered '23 Jan 2021 08:19:37'	System	23 Jan 2021 13:19:40
	System	23 Jan 2021 13:19:40

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-01-30T11:58:54', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '0cf9953d-48e4-466d-a977-ec6b78aeb13a' User entered 'No (N)'	System	30 Jan 2021 16:59:04
	System	30 Jan 2021 16:59:04

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-01-30T11:58:55', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '0cf9953d-48e4-466d-a977-ec6b78aeb13a' User entered 'No (N)'	System	30 Jan 2021 16:59:04



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-01-30T11:58:57', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '0cf9953d-48e4-466d-a977-ec6b78aeb13a' User entered '30 Jan 2021 11:58:57'	System	30 Jan 2021 16:59:04
	System	30 Jan 2021 16:59:04

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:03:00

US3742225

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-02-06T10:25:10', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'eb105fcb-b591-489c-a228-17380af016fc' User entered 'No (N)'	System	06 Feb 2021 15:25:18
	System	06 Feb 2021 15:25:18

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-02-06T10:25:11', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'eb105fcb-b591-489c-a228-17380af016fc' User entered 'No (N)'	System	06 Feb 2021 15:25:18
	System	06 Feb 2021 15:25:18

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-02-06T10:25:13', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'eb105fcb-b591-489c-a228-17380af016fc' User entered '06 Feb 2021 10:25:13'	System	06 Feb 2021 15:25:18
	System	06 Feb 2021 15:25:18

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-02-13T08:27:46', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '39785b79-2c12-4721-974f-d99ef1246238' User entered 'No (N)'	System	13 Feb 2021 13:27:52
	System	13 Feb 2021 13:27:52

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-02-13T08:27:48', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '39785b79-2c12-4721-974f-d99ef1246238' User entered 'No (N)'	System	13 Feb 2021 13:27:52
	System	13 Feb 2021 13:27:52

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-02-13T08:27:51', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '39785b79-2c12-4721-974f-d99ef1246238' User entered '13 Feb 2021 08:27:51'	System	13 Feb 2021 13:27:52
	System	13 Feb 2021 13:27:52

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-02-20T09:31:16', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'd87db4ce-aca9-44e3-98aa-98ef5bc2fbc0' User entered 'No (N)'	System	20 Feb 2021 14:31:20
	System	20 Feb 2021 14:31:20

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-02-20T09:31:17', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'd87db4ce-aca9-44e3-98aa-98ef5bc2fbc0' User entered 'No (N)'	System	20 Feb 2021 14:31:20
	System	20 Feb 2021 14:31:20

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-02-20T09:31:19', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'd87db4ce-aca9-44e3-98aa-98ef5bc2fbc0' User entered '20 Feb 2021 09:31:19'	System	20 Feb 2021 14:31:20
	System	20 Feb 2021 14:31:20

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:03:00

US3742225

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-02-27T09:41:26-05:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '5d9e7b1b-c34f-49e4-adcd-3ea895c91320'	System	27 Feb 2021 14:41:34
User entered 'No (N)'	System	27 Feb 2021 14:41:34

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-02-27T09:41:27-05:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '5d9e7b1b-c34f-49e4-adcd-3ea895c91320'	System	27 Feb 2021 14:41:34
User entered 'No (N)'	System	27 Feb 2021 14:41:34



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-02-27T09:41:29-05:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '5d9e7b1b-c34f-49e4-adcd-3ea895c91320'	System	27 Feb 2021 14:41:34
User entered '27 Feb 2021 14:41:29'	System	27 Feb 2021 14:41:34

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:03:00

US3742225

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-03-06T10:27:48-05:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'a16f6567-d257-4f47-a078-01bf8dc09a5d'	System	06 Mar 2021 15:27:54
User entered 'No (N)'	System	06 Mar 2021 15:27:54

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-03-06T10:27:49-05:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'a16f6567-d257-4f47-a078-01bf8dc09a5d'	System	06 Mar 2021 15:27:54
User entered 'No (N)'	System	06 Mar 2021 15:27:54

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-03-06T10:27:51-05:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'a16f6567-d257-4f47-a078-01bf8dc09a5d' User entered '06 Mar 2021 10:27:51'	System	06 Mar 2021 15:27:54
	System	06 Mar 2021 15:27:54

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-03-13T09:40:42-05:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '9c9652c4-dc35-4f54-b68f-bf98f527a5bd' User entered 'No (N)'	System	13 Mar 2021 14:40:50
	System	13 Mar 2021 14:40:50

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-03-13T09:40:43-05:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '9c9652c4-dc35-4f54-b68f-bf98f527a5bd'	System	13 Mar 2021 14:40:50
User entered 'No (N)'	System	13 Mar 2021 14:40:50

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-03-13T09:40:46-05:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '9c9652c4-dc35-4f54-b68f-bf98f527a5bd' User entered '13 Mar 2021 09:40:46'	System	13 Mar 2021 14:40:50
	System	13 Mar 2021 14:40:50

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:03:00



US3742225

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-03-20T09:55:49-04:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '6a06d2ad-0b3b-408a-aae8-1afa2320968e' User entered 'No (N)'	System	20 Mar 2021 13:55:56
	System	20 Mar 2021 13:55:56

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-03-20T09:55:50-04:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '6a06d2ad-0b3b-408a-aae8-1afa2320968e' User entered 'No (N)'	System	20 Mar 2021 13:55:56
	System	20 Mar 2021 13:55:56

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-03-20T09:55:54-04:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '6a06d2ad-0b3b-408a-aae8-1afa2320968e' User entered '20 Mar 2021 09:55:54'	System	20 Mar 2021 13:55:56
	System	20 Mar 2021 13:55:56

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:03:00

US3742225

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-03-27T10:01:38-04:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '9d2d2f45-1e27-4940-a35f-1c10015d6fd1' User entered 'No (N)'	System	31 Mar 2021 12:19:58
	System	31 Mar 2021 12:19:58

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-03-27T10:01:41-04:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '9d2d2f45-1e27-4940-a35f-1c10015d6fd1'	System	31 Mar 2021 12:19:58
User entered 'No (N)'	System	31 Mar 2021 12:19:58



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-03-27T10:01:43-04:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '9d2d2f45-1e27-4940-a35f-1c10015d6fd1' User entered '27 Mar 2021 10:01:43'	System	31 Mar 2021 12:19:58
	System	31 Mar 2021 12:19:58

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:03:00

US3742225

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-04-03T07:50:06-04:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '8e7ea568-4257-45b8-a5ee-7322aab58466' User entered 'No (N)'	System	03 Apr 2021 11:50:13
	System	03 Apr 2021 11:50:13

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-04-03T07:50:07-04:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '8e7ea568-4257-45b8-a5ee-7322aab58466' User entered 'No (N)'	System	03 Apr 2021 11:50:13

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-04-03T07:50:09-04:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '8e7ea568-4257-45b8-a5ee-7322aab58466' User entered '03 Apr 2021 07:50:09'	System	03 Apr 2021 11:50:13
	System	03 Apr 2021 11:50:13

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:03:00

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-04-12T12:28:37-04:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '927ec6b6-bd4a-4899-8104-43b2cd2dff14' User entered 'No (N)'	System	12 Apr 2021 16:28:44
	System	12 Apr 2021 16:28:44

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-04-12T12:28:39-04:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '927ec6b6-bd4a-4899-8104-43b2cd2dff14' User entered 'No (N)'	System	12 Apr 2021 16:28:44
	System	12 Apr 2021 16:28:44

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-04-12T12:28:41-04:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '927ec6b6-bd4a-4899-8104-43b2cd2dff14'	System	12 Apr 2021 16:28:44
User entered '12 Apr 2021 12:28:41'	System	12 Apr 2021 16:28:44

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-04-17T10:16:46-04:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '5b9997f1-15fe-40b5-a266-bd65000b72c9' User entered 'Yes (Y)'	System	24 Apr 2021 14:33:14
	System	24 Apr 2021 14:33:14

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-04-17T10:16:49-04:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '5b9997f1-15fe-40b5-a266-bd65000b72c9' User entered 'No (N)'	System	24 Apr 2021 14:33:14
	System	24 Apr 2021 14:33:14

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-04-17T10:16:51-04:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '5b9997f1-15fe-40b5-a266-bd65000b72c9' User entered 'No (N)'	System	24 Apr 2021 14:33:14
	System	24 Apr 2021 14:33:14

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-04-17T10:16:58-04:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '5b9997f1-15fe-40b5-a266-bd65000b72c9' User entered 'No (N)'	System	24 Apr 2021 14:33:14
	System	24 Apr 2021 14:33:14

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-04-17T10:17:01-04:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '5b9997f1-15fe-40b5-a266-bd65000b72c9'	System	24 Apr 2021 14:33:14
User entered '17 Apr 2021 10:17:01'	System	24 Apr 2021 14:33:14

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:03:00



US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-04-24T10:33:09-04:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '77353de6-8c05-4f1f-853a-faad39d3660c' User entered 'No (N)'	System	24 Apr 2021 14:33:16
	System	24 Apr 2021 14:33:16

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-04-24T10:33:11-04:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '77353de6-8c05-4f1f-853a-faad39d3660c' User entered 'No (N)'	System	24 Apr 2021 14:33:16

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-04-24T10:33:13-04:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '77353de6-8c05-4f1f-853a-faad39d3660c' User entered '24 Apr 2021 10:33:13'	System	24 Apr 2021 14:33:16
	System	24 Apr 2021 14:33:16

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:03:00

US3742225

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-05-01T11:35:55-04:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'ab8f0d5a-1594-4ea9-92fc-fff19b2dcdb8'	System	01 May 2021 15:36:06
User entered 'No (N)'	System	01 May 2021 15:36:06

US3742225

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:29:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-05-01T11:35:57-04:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'ab8f0d5a-1594-4ea9-92fc-fff19b2dcdb8'	System	01 May 2021 15:36:06
User entered 'No (N)'	System	01 May 2021 15:36:06



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-05-01T11:36:00-04:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: 'ab8f0d5a-1594-4ea9-92fc-fff19b2dcdb8'	System	01 May 2021 15:36:06
User entered '01 May 2021 11:36:00'	System	01 May 2021 15:36:06

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:03:00

US3742225

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:03:00



**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 03:03:00

**US3742225**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:29:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:03:00
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 03:03:00



US3742225

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:29:59**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-03-06T10:27:56-05:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '3aed9de1-a2d7-40af-8bf2-e188cb1c06f5'	System	06 Mar 2021 15:28:00
User entered 'No (N)'	System	06 Mar 2021 15:28:00

US3742225

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:29:59

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6845324D-714D-4D6C-A082-8A9979340A43)', Time: '2021-03-06T10:27:59-05:00', User OID: 'PatientReportedOutcome (US3742225)', ODM File OID: '3aed9de1-a2d7-40af-8bf2-e188cb1c06f5' User entered '06 Mar 2021 10:27:59'	System	06 Mar 2021 15:28:00
	System	06 Mar 2021 15:28:00

US3742225

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:10:04
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	25 Nov 2020 17:39:20

US3742225

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:10:04
User entered '25 Nov 2020'	Sherry McCammon (b) (4) (b) (4)	25 Nov 2020 17:39:20

US3742225

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:10:04
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4) (b) (4)	25 Nov 2020 17:39:20

US3742225

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:10:04
User entered empty.	Sherry McCammon (b) (4) (b) (4)	25 Nov 2020 17:39:20

US3742225

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:10:10
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	25 Nov 2020 17:39:25

US3742225

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:12
User entered '1'	System	25 Nov 2020 17:39:25



US3742225

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:33:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:58:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	22 Feb 2021 15:20:38
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Feb 2021 16:05:59
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	29 Jan 2021 16:55:39
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 16:55:39
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	(b) (4), (b) (6)	29 Jan 2021 16:53:27
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 16:52:53
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	29 Jan 2021 16:52:53
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 16:52:53
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 16:51:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jan 2021 16:51:30
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	29 Jan 2021 16:51:30

US3742225

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 16:51:30
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Jan 2021 19:41:27
User entered empty.	Kaitlin Mason (b) (4)	27 Jan 2021 19:41:27
	(b) (4)	

US3742225

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:33:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:58:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '29 Dec 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:55:39
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 16:52:53
User entered '29 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 16:51:30
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	27 Jan 2021 19:41:27

US3742225

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:33:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:58:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	22 Feb 2021 15:20:38
reason for change: Data Entry Error	(b) (4), (b) (6)	
User entered empty.	Kaitlin Mason (b) (4)	27 Jan 2021 19:41:27
	(b) (4)	

US3742225

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:33:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:58:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered empty.	(b) (4) Kaitlin Mason (b) (4) (b) (4)	27 Jan 2021 19:41:27

US3742225

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:33:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:58:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 Feb 2021 16:02:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 16:58:34
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	(b) (4), (b) (6)	29 Jan 2021 16:53:13
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 16:53:04
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 16:53:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Jan 2021 16:51:39

US3742225

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:33:55
User entered '1'	System	29 Jan 2021 16:58:34
User entered empty.	System	29 Jan 2021 16:53:04
User entered '1'	System	29 Jan 2021 16:51:39

US3742225

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:33:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:57:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:58:58



US3742225

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:33:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:57:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:58:58

US3742225

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:33:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:57:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:58:58

US3742225

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:33:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:57:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:58:58

US3742225

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:33:55
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:57:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:59:14

US3742225

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:33:55
User entered 'I'	System	29 Jan 2021 16:59:14

US3742225

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:16:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
User entered 'Yes (Y)'	(b) (4)	26 Feb 2021 20:02:48
	(b) (4), (b) (6)	

US3742225

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:16:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:02:48

US3742225

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:16:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:02:48



US3742225

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:16:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:42
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:02:48

US3742225

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:16:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:36:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
User entered 'Yes (Y)'	(b) (4)	26 Feb 2021 20:03:06
	(b) (4), (b) (6)	

US3742225

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:16:01
User entered 'I'	System	26 Feb 2021 20:03:06

US3742225

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:24:55

US3742225

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
User entered '6 Apr 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:24:55

US3742225

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:24:55

**US3742225**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:29:59**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	06 Apr 2021 15:24:55

US3742225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:25:05



US3742225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:25:05

US3742225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:25:05

US3742225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 15:25:05

US3742225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:25:05

US3742225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:25:05

US3742225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:25:05

US3742225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:25:05

US3742225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 15:25:05



US3742225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:25:05

US3742225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 15:25:05

US3742225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:25:05

US3742225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 15:25:05

US3742225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:25:05

US3742225

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:29:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 15:25:05

US3742225

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:59

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:25:18

US3742225

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:25:18



US3742225

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:25:47

US3742225

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
User entered '6 Apr 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:25:47

US3742225

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
User entered '10:26'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:25:47

US3742225

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '6 Apr 2021 10:26'	System	06 Apr 2021 15:25:47

US3742225

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:25:55

**US3742225**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:29:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 15:25:55

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:15
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:34:10

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:15
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:34:10



US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:59

[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 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:15
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:34:10

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 18:34:10

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:59

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:37:30
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:33:37
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 16:33:37
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 16:33:37
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '6 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:36:11

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:59

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:37:30
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:42:56
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 16:33:37
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:27:16

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:59

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:36:11

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:59

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:37:30
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:42:56
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	12 Apr 2021 16:33:37
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:27:16

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:59

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:36:11

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:59

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:36:11



US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:59

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 13:55:08
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	15 Jan 2021 18:36:11

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:59

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 13:55:08
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	15 Jan 2021 18:36:11

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:59

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:36:11

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:59

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User entered '1'	System	15 Jan 2021 18:36:11

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:29:59

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User entered 'I'	System	15 Jan 2021 18:36:11

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User entered empty.	System	15 Jan 2021 18:40:39
DataPoint set to visible.	System	15 Jan 2021 18:36:11



US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User entered empty.	System	15 Jan 2021 18:40:39
DataPoint set to visible.	System	15 Jan 2021 18:36:11

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '10:48'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User entered '14 Jan 2021 10:48'	System	15 Jan 2021 18:40:39



US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '093'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User entered 'bpm'	System	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '13'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User entered 'breaths/min'	System	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '112'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:40:39



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User entered 'mmHg'	System	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '069'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User entered 'mmHg'	System	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:29:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User entered empty.	System	15 Jan 2021 18:40:39
DataPoint set to visible.	System	15 Jan 2021 18:36:11

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:40:39



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '11:30'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User entered '14 Jan 2021 11:30'	System	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:40:39

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)   	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '085'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User entered 'bpm'	System	15 Jan 2021 18:40:39



US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '18'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User entered 'breaths/min'	System	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '118'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:40:39

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User entered 'mmHg'	System	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '073'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User entered 'mmHg'	System	15 Jan 2021 18:40:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:37:39

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:00:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:37:39



US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:01:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:37:27

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:01:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:37:27

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:01:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:37:27

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:01:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:37:27

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:01:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:37:27

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:01:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:37:27

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:01:01
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:37:27

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User entered empty.	System	15 Jan 2021 18:37:27



US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:01:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:38:11

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:01:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered empty.	(b) (4)	15 Jan 2021 18:38:11
	(b) (4), (b) (6)	

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:01:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:38:11

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User entered 'mRNA-1273'	System	15 Jan 2021 18:38:11
DataPoint set to visible.	System	15 Jan 2021 18:36:11

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:01:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:38:11

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:01:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '10:58'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:38:11

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User entered '14 Jan 2021 10:58'	System	15 Jan 2021 18:38:11

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:01:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:38:11



US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:01:08
User entered 'ONCE'	System	15 Jan 2021 18:38:11

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User entered 'INTRAMUSCULAR'	System	15 Jan 2021 18:38:11

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:01:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:35:27

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:01:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:35:27

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:01:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '10:27'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:35:27

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User entered '14 Jan 2021 10:27'	System	15 Jan 2021 18:35:27

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:29:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:01:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:35:45

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:29:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:01:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:35:45



US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:29:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:01:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '10:32'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:35:45

US3742225

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:29:59**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User entered '14 Jan 2021 10:32'	System	15 Jan 2021 18:35:45

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:01:27
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 18:37:45

US3742225

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:12:36
User entered '1'	System	15 Jan 2021 18:37:45

US3742225

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:58:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4) (b) (4)	22 Jan 2021 18:18:48

US3742225

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:58:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '21 Jan 2021'	(b) (4) Sherry McCammon (b) (4) (b) (4)	22 Jan 2021 18:18:48

US3742225

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:58:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	22 Jan 2021 18:18:48

US3742225

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:58:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered empty.	(b) (4) Sherry McCammon (b) (4)	22 Jan 2021 18:18:48



US3742225

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:59:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4) (b) (4)	22 Jan 2021 18:18:54

US3742225

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:43:28
User entered 'I'	System	22 Jan 2021 18:18:54

US3742225

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:43:28
User entered '1'	System	22 Jan 2021 18:18:54
DataPoint set to visible.	System	22 Jan 2021 18:18:54

US3742225

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:01:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:47:22

US3742225

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:01:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:47:22

US3742225

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:01:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:47:22

US3742225

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:29:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
User entered 'OLD29'	System	10 Feb 2021 14:47:22

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Feb 2021 14:51:32



US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:51:32

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:51:32

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '10:25'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:51:32

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
User entered '9 Feb 2021 10:25'	System	10 Feb 2021 14:51:32

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:51:32

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:51:32

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered empty.	(b) (4)	10 Feb 2021 14:51:32
	(b) (4), (b) (6)	

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '076'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:51:32



US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
User entered 'bpm'	System	10 Feb 2021 14:51:32

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '16'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:51:32

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
User entered 'breaths/min'	System	10 Feb 2021 14:51:32

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '114'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:51:32

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
User entered 'mmHg'	System	10 Feb 2021 14:51:32

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '075'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:51:32

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:29:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
User entered 'mmHg'	System	10 Feb 2021 14:51:32

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Feb 2021 14:51:32



US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:51:32

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:51:32

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '11:11'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:51:32

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
User entered '9 Feb 2021 11:11'	System	10 Feb 2021 14:51:32

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:51:32

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:51:32

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered empty.	(b) (4)	10 Feb 2021 14:51:32
	(b) (4), (b) (6)	

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '078'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:51:32



US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
User entered 'bpm'	System	10 Feb 2021 14:51:32

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '16'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:51:32

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
User entered 'breaths/min'	System	10 Feb 2021 14:51:32

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '118'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:51:32

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
User entered 'mmHg'	System	10 Feb 2021 14:51:32

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '076'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:51:32

US3742225

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:29:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
User entered 'mmHg'	System	10 Feb 2021 14:51:32

US3742225

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Yes (Y)'	(b) (4)	10 Feb 2021 14:49:01
	(b) (4), (b) (6)	



US3742225

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:49:01

US3742225

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:47:45

US3742225

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:47:45

US3742225

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:47:45

US3742225

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:47:45

US3742225

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:47:45

US3742225

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered empty.	(b) (4)	10 Feb 2021 14:47:45
	(b) (4), (b) (6)	

US3742225

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:03:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered empty.	(b) (4)	10 Feb 2021 14:47:45
	(b) (4), (b) (6)	



US3742225

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:29:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
User entered empty.	System	10 Feb 2021 14:47:45

US3742225

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:49:43

US3742225

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered empty.	(b) (4)	10 Feb 2021 14:49:43
	(b) (4), (b) (6)	

US3742225

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered empty.	(b) (4)	10 Feb 2021 14:49:43
	(b) (4), (b) (6)	

US3742225

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
User entered 'mRNA-1273'	System	10 Feb 2021 14:49:43
DataPoint set to visible.	System	22 Jan 2021 18:18:54

US3742225

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:49:43

US3742225

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '10:40'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:49:43

US3742225

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
User entered '9 Feb 2021 10:40'	System	10 Feb 2021 14:49:43



US3742225

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:49:43

US3742225

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:06
User entered 'ONCE'	System	10 Feb 2021 14:49:43

US3742225

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:29:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
User entered 'INTRAMUSCULAR'	System	10 Feb 2021 14:49:43

US3742225

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:12
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:47:30

US3742225

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:09:32
User entered 'I'	System	10 Feb 2021 14:47:30

US3742225

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:59:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:06:34

US3742225

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:59:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '16 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:06:34

US3742225

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:59:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:06:34



US3742225

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:29:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:59:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:06:34

US3742225

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:59:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:06:43

US3742225

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:29:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:43:28
User entered 'I'	System	17 Feb 2021 17:06:43

US3742225

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	06 Apr 2021 15:23:09

US3742225

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:29:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 15:23:09

US3742225

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:23:40

US3742225

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
User entered '6 Apr 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:23:40

US3742225

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:29:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:42
User entered '10:26'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:23:40



**US3742225**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:29:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '6 Apr 2021 10:26'	System	06 Apr 2021 15:23:40

US3742225

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:29:59

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:05:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:27:52

US3742225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
	(b) (4)	
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Neurological disorders congenital, HLT: Cerebellar disorders congenital, PT: Arnold-Chiari malformation, LLT: Chiari malformation - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 20:59:00
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 20:59:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 20:05:20
Data point term sent to Coder	System	23 Feb 2021 18:58:28
User entered 'cHIARI MALFORMATION TYPE 1.5' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	23 Feb 2021 18:58:17
	(b) (4)	
Data point term sent to Coder	System	23 Feb 2021 16:05:47
User entered 'shiari malformation type 1.5'	Sherry McCammon (b) (4)	23 Feb 2021 16:05:14
	(b) (4)	

US3742225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:05:20
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	23 Feb 2021 16:05:14

US3742225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:05:20
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	23 Feb 2021 16:05:14

US3742225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:04:31
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
User closed query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' (Site from Safety). Query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' answered with 'entered in error' (Site from Safety).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 15:29:13
DataPoint Un-verified.	Kaitlin Mason (b) (4)	24 Feb 2021 13:19:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Kaitlin Mason (b) (4)	24 Feb 2021 13:19:10 24 Feb 2021 13:19:10
User opened query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 00:42:15
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:05:20
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Feb 2021 16:05:14

US3742225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 20:05:20
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 18:58:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Feb 2021 18:58:17
User entered '15 Dec 2020' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	23 Feb 2021 18:58:17
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 16:06:13
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	23 Feb 2021 16:06:13
	(b) (4)	
User entered '15 Dec 2020'	Sherry McCammon (b) (4)	23 Feb 2021 16:05:14
	(b) (4)	

US3742225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 20:05:20
User entered empty.	Sherry McCammon (b) (4)	23 Feb 2021 16:05:14
	(b) (4)	



US3742225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Feb 2021 16:05:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 19:27:46
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 19:27:46
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	29 Apr 2021 19:27:46
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 15:22:06
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'Ongoing' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 17:13:36
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 18:05:54
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 20:05:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Feb 2021 16:05:45
User entered 'No (N)'	(b) (4)	
	Sherry McCammon (b) (4)	23 Feb 2021 16:05:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 19:27:46
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 19:27:46
User entered '17 Apr 2021' reason for change: New Information	(b) (4), (b) (6)	29 Apr 2021 19:27:46
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 20:05:20
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	23 Feb 2021 16:05:45
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	23 Feb 2021 16:05:14
User entered empty.	Sherry McCammon (b) (4)	23 Feb 2021 16:05:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:05:20
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Feb 2021 16:05:14

**US3742225**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:29:59**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Feb 2021 16:05:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:05:20
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sherry McCammon (b) (4) (b) (4)	23 Feb 2021 16:05:14

US3742225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 20:05:20
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 16:05:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Feb 2021 16:05:45
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Feb 2021 16:05:45
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 16:05:14
User entered empty.	Sherry McCammon (b) (4)	23 Feb 2021 16:05:14
	(b) (4)	

US3742225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 20:05:20
User entered '0'	Sherry McCammon (b) (4)	23 Feb 2021 16:05:14
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 20:05:20
User entered '0'	Sherry McCammon (b) (4)	23 Feb 2021 16:05:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:05:20
User entered '0'	Sherry McCammon (b) (4) (b) (4)	23 Feb 2021 16:05:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:05:20
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Feb 2021 16:05:14

US3742225

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:05:20
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Feb 2021 16:05:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:05:20
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Feb 2021 16:05:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:05:20
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Feb 2021 16:05:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 20:05:20
User entered '0'	Sherry McCammon (b) (4)	23 Feb 2021 16:05:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 20:05:20
User entered '0'	Sherry McCammon (b) (4)	23 Feb 2021 16:05:14
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 20:05:20
User entered '0'	Sherry McCammon (b) (4)	23 Feb 2021 16:05:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:05:20
User entered 'Not Related (NOT RELATED)'	Sherry McCammon (b) (4) (b) (4)	23 Feb 2021 16:05:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 20:05:20
User entered 'Not Related (NOT RELATED)'	Sherry McCammon (b) (4)	23 Feb 2021 16:05:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:05:20
User entered 'Not Applicable (NOT APPLICABLE)'	Sherry McCammon (b) (4) (b) (4)	23 Feb 2021 16:05:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 20:05:20
User entered 'I'	Sherry McCammon (b) (4)	23 Feb 2021 16:05:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 20:05:20
User entered '0'	Sherry McCammon (b) (4)	23 Feb 2021 16:05:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 20:05:20
User entered '0'	Sherry McCammon (b) (4)	23 Feb 2021 16:05:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 19:27:46
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 19:27:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	29 Apr 2021 19:27:46
New Information		
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 20:05:20
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Sherry McCammon (b) (4)	23 Feb 2021 16:05:14
	(b) (4)	



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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 20:05:20
User entered empty.	Sherry McCammon (b) (4)	23 Feb 2021 16:05:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:29:59

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 20:05:20
User entered empty.	Sherry McCammon (b) (4)	23 Feb 2021 16:05:14
	(b) (4)	

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**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 10 Jun 2021 09:29:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	23 Feb 2021 16:05:45

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**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 10 Jun 2021 09:29:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	23 Feb 2021 16:05:14

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 20:48:24
User entered		
'USA-US127-2021-mRNA-1273-P301000017'	System	29 Apr 2021 20:48:21
User entered 'New'	(b) (4), (b) (6)	29 Apr 2021 20:48:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:59

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
	(b) (4)	
User coded data point as SOC: Congenital, familial and genetic disorders, HLG: Neurological disorders congenital, HLT: Cerebellar disorders congenital, PT: Arnold-Chiari malformation, LLT: Arnold-Chiari malformation - version MedDRA\\23.0.	Coder Import (b) (4)	29 Apr 2021 22:57:16
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Apr 2021 22:57:16
	(b) (4)	
Data point term sent to Coder	System	29 Apr 2021 18:09:37
User entered 'ARNOLD CHIARI SYNDROME'	(b) (4), (b) (6)	29 Apr 2021 18:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:09:20



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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:29:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered '14 Apr 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 18:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:09:20

US3742225

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:59

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered '17 Apr 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:59

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:09:20

**US3742225**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:29:59**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 18:09:20



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:59

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:09:20

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:29:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:09:20

US3742225

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:09:20

US3742225

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:09:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered '14 Apr 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:09:20

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:29:59

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered '17 Apr 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:09:20

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:29:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:09:20



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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered '1'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:09:20

US3742225

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:09:20

US3742225

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:09:20

US3742225

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:09:20

US3742225

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:09:20

US3742225

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:09:20

US3742225

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:09:20

US3742225

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:59

None

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 18:09:24
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	30 Apr 2021 18:05:23
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Apr 2021 18:05:23
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	30 Apr 2021 14:57:19
User entered '1' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	30 Apr 2021 14:57:19
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	29 Apr 2021 18:09:20
User entered '0'	(b) (4), (b) (6)	29 Apr 2021 18:09:20



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 18:09:24
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	30 Apr 2021 18:05:23
User entered '1' reason for change: New Information	(b) (4), (b) (6)	30 Apr 2021 18:05:23
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 18:09:20

US3742225

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 18:09:24
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	30 Apr 2021 18:05:23
User entered '1' reason for change: New Information	(b) (4), (b) (6)	30 Apr 2021 18:05:23
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 18:09:20

US3742225

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:59

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:09:20

US3742225

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:09:20

US3742225

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:59

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 16:57:16
User entered 'IN JANUARY 2020 AND WAS SCHEDULED TO HAVE SURGERY ON 14 APR 2021. ADMITTED TO THE HOSPITAL ON 14 APR 2021 WITH A PRE-OP DIAGNOSIS OF ARNOLD CHIARI SYNDROME. HAD SURGICAL PROCEDURE OF SUBOCCIPITAL DECOMPRESSION WITH PERICRANAL GRAFT. WAS ADMITTED TO THE ICU POST-OP DUE TO MED HX OF POSTURAL TACHYCARDIA AND EHLERS DANLOS SYNDROME. WAS DISCHARGED HOME ON 17 APR 2021.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 18:09:20
SAE IS SURGERY FOR CONGENITAL CHIARI SYNDROME THAT BECAME SYMPTOMATIC, PROMPTING HER TO EVENTUALLY DECIDE TO HAVE SURGERY. IT IS THE ELECTIVE SURGERY THAT QUALIFIES THIS AS AN SAE.'		

US3742225

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 10 Jun 2021 09:29:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 18:09:20

US3742225

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 10 Jun 2021 09:29:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 18:09:20

US3742225

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:29:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 18:09:20



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:29:59

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:25
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 14:59:10

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:02:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 15:03:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 15:03:46
Data point term sent to Coder	System	03 Sep 2020 15:02:49
User entered 'duloxetine'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:02:31

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:02:31

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:29:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'anxiety'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:02:31

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:29:59**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered '60'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:02:31

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'mg (mg)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:02:31

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:29:59**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:02:31

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:29:59**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'once daily (QD)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:02:31



US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:29:59**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:02:31

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:29:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'Oral (ORAL)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:02:31

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:29:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:02:31

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:29:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'UN May 2020'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:02:31

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:29:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:02:31

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:47:12
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 18:47:12
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:02:31

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:29:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:47:12
User entered '28 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 18:47:12
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:02:31

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:29:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:02:31



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:29:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 15:02:31

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:29:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 15:02:31

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:29:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 15:02:31

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:02:49
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 15:52:44
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 15:52:44
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 15:18:38
User entered 'monteleukast'	Hassan Haji (b) (4)	03 Sep 2020 15:17:40
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:17:40

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'allergies environmental'	Hassan Haji (b) (4)	03 Sep 2020 15:17:40
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:29:59**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered '10'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:17:40

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'mg (mg)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:17:40



US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:29:59**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:17:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'once daily (QD)'	Hassan Haji (b) (4)	03 Sep 2020 15:17:40
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:29:59**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:17:40

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:29:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'Oral (ORAL)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:17:40

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:29:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:17:40

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:29:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'UN UNK 2016'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:17:40

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:29:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:17:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:17:40



US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:29:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:17:40

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:29:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:17:40

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:29:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 15:17:40

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:29:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 15:17:40

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:29:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 15:17:40

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:02:49
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 03:54:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 03:54:10
Data point term sent to Coder	System	03 Sep 2020 15:21:43
User entered 'zyrtec'	Hassan Haji (b) (4)	03 Sep 2020 15:20:43
	(b) (4)	

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:20:43

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'allergies environmental'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:20:43



US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered '10'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:20:43

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'mg (mg)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:20:43

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:29:59**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:20:43

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:29:59**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'once daily (QD)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:20:43

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:29:59**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:20:43

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:29:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'Oral (ORAL)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:20:43

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:29:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:20:43

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:29:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'UN UNK 2016'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:20:43



US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:20:43

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:29:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:20:43

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:29:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:20:43

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:29:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:20:43

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:29:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 15:20:43

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:29:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 15:20:43

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:29:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 15:20:43

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:02:49
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 15:25:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 15:25:48
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 15:24:51
User entered 'albuterol inhaler'	Hassan Haji (b) (4)	03 Sep 2020 15:24:08
	(b) (4)	



US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:24:08

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'asthma'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:24:08

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:02:49
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 15:28:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 15:28:11
User entered '180' reason for change: Data Entry Error	Hassan Haji (b) (4)	03 Sep 2020 15:28:11
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 15:24:08
User entered empty.	Hassan Haji (b) (4)	03 Sep 2020 15:24:08
	(b) (4)	

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:02:49
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 15:28:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 15:28:11
User entered 'mg (mg)' reason for change: Data Entry Error	Hassan Haji (b) (4)	03 Sep 2020 15:28:11
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 15:24:08
User entered empty.	Hassan Haji (b) (4)	03 Sep 2020 15:24:08
	(b) (4)	

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:29:59**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:24:08

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'as needed (PRN)'	Hassan Haji (b) (4)	03 Sep 2020 15:24:08
	(b) (4)	

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:29:59**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:24:08

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:24:08



US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:29:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:24:08

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:29:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'UN UNK 1999'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:24:08

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:29:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered '0'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:24:08

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:24:08

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:29:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:24:08

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:29:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:02:49
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 15:28:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 15:28:11
User entered 'No (N)' reason for change: Data Entry Error	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:28:11
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 15:24:08
User entered empty.	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 15:24:08

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:29:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 15:24:08

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:29:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 15:24:08



US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:29:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 15:24:08

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:38:25
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: KYLEENA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 05:22:29
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 05:22:29
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 17:31:46
User entered 'LEVONORGESTREL KLYEENA IUD'	Sherry McCammon (b) (4)	21 Oct 2020 17:31:29
	(b) (4)	

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 09:08:13
' (Site from DM).		
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4), (b) (6)	22 Feb 2021 15:12:13
' answered with 'updated' (Site from DM).		
DataPoint Un-verified.	(b) (4), (b) (6)	22 Feb 2021 15:12:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 15:12:04
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4), (b) (6)	07 Jan 2021 21:02:44
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:38:25
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	21 Oct 2020 17:31:29

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:38:25
User entered 'CONTRACEPTION'	Sherry McCammon (b) (4) (b) (4)	21 Oct 2020 17:31:29

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:29:59**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:38:25
User entered '19.5'	Sherry McCammon (b) (4)	21 Oct 2020 17:31:29
	(b) (4)	

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:38:25
User entered 'mg (mg)'	Sherry McCammon (b) (4) (b) (4)	21 Oct 2020 17:31:29

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:38:25
User entered empty.	Sherry McCammon (b) (4) (b) (4)	21 Oct 2020 17:31:29

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
User closed query 'Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 09:08:16
Query 'Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 15:15:09
DataPoint Un-verified.	(b) (4), (b) (6)	22 Feb 2021 15:15:01
User entered 'other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 15:15:01
User opened query 'Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 21:03:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:38:25
User entered 'once (ONCE)'	Sherry McCammon (b) (4) (b) (4)	21 Oct 2020 17:31:29



US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:15:01
User entered 'Every five years' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 15:15:01
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:38:25
User entered empty.	Sherry McCammon (b) (4) (b) (4)	21 Oct 2020 17:31:29

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:38:25
User entered 'Other (OTHER)'	Sherry McCammon (b) (4)	21 Oct 2020 17:31:29
	(b) (4)	

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:29:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:38:25
User entered 'INTERUTERINE'	Sherry McCammon (b) (4) (b) (4)	21 Oct 2020 17:31:29

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:38:25
User entered 'UN Aug 2017'	Sherry McCammon (b) (4)	21 Oct 2020 17:31:29
	(b) (4)	

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:29:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 18:38:25
User entered '0'	Sherry McCammon (b) (4)	21 Oct 2020 17:31:29
	(b) (4)	

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:38:25
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	21 Oct 2020 17:31:29

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:38:25
User entered empty.	Sherry McCammon (b) (4) (b) (4)	21 Oct 2020 17:31:29

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:29:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:38:25
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	21 Oct 2020 17:31:29



US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:29:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:31:29

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:29:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:31:29

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:29:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:31:29

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 19:10:33
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 17:42:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 17:42:17
Data point term sent to Coder	System	25 Nov 2020 17:41:28
User entered 'INFLUENZA VACCINE'	Sherry McCammon (b) (4)	25 Nov 2020 17:41:15
	(b) (4)	

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:10:33
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	25 Nov 2020 17:41:15

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:29:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:10:33
User entered 'INFLUENZA PROPHYLAXIS'	Sherry McCammon (b) (4) (b) (4)	25 Nov 2020 17:41:15

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:29:59**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:10:33
User entered '0.5'	Sherry McCammon (b) (4) (b) (4)	25 Nov 2020 17:41:15

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:29:59**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:10:33
User entered 'mL (mL)'	Sherry McCammon (b) (4) (b) (4)	25 Nov 2020 17:41:15



US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:29:59**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:10:33
User entered empty.	Sherry McCammon (b) (4) (b) (4)	25 Nov 2020 17:41:15

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:10:33
User entered 'once (ONCE)'	Sherry McCammon (b) (4) (b) (4)	25 Nov 2020 17:41:15

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:29:59**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:10:33
User entered empty.	Sherry McCammon (b) (4) (b) (4)	25 Nov 2020 17:41:15

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:29:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:10:33
User entered 'Intramuscular (INTRAMUSCULAR)'	Sherry McCammon (b) (4) (b) (4)	25 Nov 2020 17:41:15

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:29:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:10:33
User entered empty.	Sherry McCammon (b) (4) (b) (4)	25 Nov 2020 17:41:15

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:10:33
User entered '22 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	25 Nov 2020 17:41:15

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:29:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 19:10:33
User entered '0'	Sherry McCammon (b) (4)	25 Nov 2020 17:41:15
	(b) (4)	

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:29:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:10:33
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	25 Nov 2020 17:41:15



US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:29:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:10:33
User entered '22 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	25 Nov 2020 17:41:15

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:29:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:10:33
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	25 Nov 2020 17:41:15

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:29:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 17:41:15

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:29:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 17:41:15

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:29:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 17:41:15

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:59

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: This Con Med had dose increased on 28 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 08:28:07
Query 'Per DM CLR: This Con Med had dose increased on 28 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' answered with 'No AE for worsening or exacerbated condition.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 17:10:42
User opened query 'Per DM CLR: This Con Med had dose increased on 28 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 03:12:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Jan 2021 18:50:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 18:50:21
Data point term sent to Coder	System	29 Jan 2021 18:50:09
User entered 'Duloxetine'	(b) (4), (b) (6)	29 Jan 2021 18:49:25

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:49:25

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
User entered 'Anxiety'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:49:25



US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
User entered '90'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:49:25

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:49:25

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:59

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
User entered empty.	(b) (4)	29 Jan 2021 18:49:25
	(b) (4), (b) (6)	

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:49:25

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:49:25

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:49:25

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
User entered empty.	(b) (4)	29 Jan 2021 18:49:25
	(b) (4), (b) (6)	

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:49:25



US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:49:25

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:49:25

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
User entered empty.	(b) (4)	29 Jan 2021 18:49:25
	(b) (4), (b) (6)	

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:29:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:41:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:49:25

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:29:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jan 2021 18:49:25

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:29:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jan 2021 18:49:25

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:29:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Jan 2021 18:49:25

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Apr 2021 21:43:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 21:43:03
Data point term sent to Coder	System	30 Apr 2021 18:20:15
User entered 'CELECOXIB' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Apr 2021 18:19:33
Data point term sent to Coder	System	30 Apr 2021 18:17:14
User entered 'CECOXIB'	(b) (4), (b) (6)	30 Apr 2021 18:16:39



US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:29:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:16:39

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:29:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'ARNOLD CHIARI SYNDROME'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:16:39

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:29:59**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered '200'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:16:39

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:29:59**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:16:39

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:29:59**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:16:39

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:29:59**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:16:39

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:29:59**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:16:39

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:29:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:16:39



US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:29:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:16:39

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:29:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered '17 Apr 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:16:39

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:29:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:16:39

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:29:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:16:39

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:29:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered '24 Apr 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:16:39

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:29:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:18:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Apr 2021 18:16:39

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:29:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Apr 2021 18:16:39

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:29:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 18:16:39



US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:29:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 18:16:39

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 May 2021 12:56:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 May 2021 12:56:39
Data point term sent to Coder	System	30 Apr 2021 18:22:16
User entered 'DEXAMETHASONE'	(b) (4), (b) (6)	30 Apr 2021 18:21:37

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:29:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 18:22:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Apr 2021 18:22:07
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Apr 2021 18:22:07
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 18:21:37
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 18:21:37

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:29:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'ARNOLD CHIARI SYNDROME'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:21:37

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:29:59**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered '4'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:21:37

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:29:59**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:21:37

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:29:59**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:21:37

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:29:59**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:21:37



US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:29:59**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:21:37

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:29:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:21:37

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:29:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:21:37

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:29:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered '17 Apr 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:21:37

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:29:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:21:37

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:29:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:21:37

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:29:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:21:37

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:29:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:21:37



US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:29:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Apr 2021 18:21:37

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:29:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 18:21:37

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:29:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 18:21:37

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:59

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 May 2021 12:56:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 12:56:39
Data point term sent to Coder	System	30 Apr 2021 18:24:20
User entered 'DEXAMETHASONE'	(b) (4), (b) (6)	30 Apr 2021 18:24:01

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:01

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:29:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'ARNOLD CHIARI SYNDROME'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:01

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:29:59**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered '2'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:01

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:29:59**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:01



US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:29:59**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:01

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:01

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:29:59**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:01

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:29:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:01

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:29:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:01

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:29:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:01

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:29:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:01

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:29:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:01



US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:29:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered '21 Apr 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:01

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:29:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:01

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:29:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Apr 2021 18:24:01

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:29:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 18:24:01

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:29:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 18:24:01

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 May 2021 12:56:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 12:56:39
Data point term sent to Coder	System	30 Apr 2021 18:26:22
User entered 'DEXAMETHASONE'	(b) (4), (b) (6)	30 Apr 2021 18:25:59

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:25:59

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'ARNOLD CHIARI SYNDROME'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:25:59



US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered '2'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:25:59

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:29:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:25:59

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:29:59**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:25:59

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:29:59**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:25:59

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:29:59**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:25:59

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:29:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:25:59

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:29:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:25:59

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:29:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered '21 Apr 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:25:59



US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:29:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:25:59

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:29:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:25:59

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:29:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered '23 Apr 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:25:59

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:29:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:25:59

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:29:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 18:25:59

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:29:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 18:25:59

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:29:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 18:25:59

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:59

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 17:05:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 17:05:11
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	01 May 2021 13:52:01
Data point term sent to Coder	System	30 Apr 2021 18:29:22
User entered 'ZOFRAN'	(b) (4), (b) (6) (b) (4)	30 Apr 2021 18:28:47



US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:29:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:28:47

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:29:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'ARNOLD CHIARI SYNDROME'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:28:47

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:29:59**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered '4'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:28:47

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:28:47

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:29:59**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:28:47

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:29:59**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:28:47

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:29:59**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:28:47

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:29:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:28:47



US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:29:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:28:47

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:29:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered '17 Apr 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:28:47

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:29:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:28:47

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:29:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:28:47

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:29:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered '20 Apr 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:28:47

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:29:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:28:47

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:29:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 18:28:47

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:29:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 18:28:47



US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:29:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 18:28:47

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:29:59

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 May 2021 17:01:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 May 2021 17:01:06
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
Data point term sent to Coder	System	30 Apr 2021 18:32:24
User entered 'TRAMADOL'	(b) (4), (b) (6)	30 Apr 2021 18:31:56

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:29:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:31:56

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:29:59**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'ARNOLD CHIARI SYNDROME'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:31:56

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:29:59**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered '50'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:31:56

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:29:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:31:56

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:29:59**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:31:56

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:29:59**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:31:56



US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:29:59**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:31:56

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:29:59**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:31:56

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:29:59**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:31:56

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:29:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered '15 Apr 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:31:56

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:29:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:31:56

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:29:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:31:56

US3742225

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:29:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:31:56

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:29:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:31:56



US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:29:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 18:31:56

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:29:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 18:31:56

US3742225

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:29:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 18:31:56

US3742225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:29:59

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:07:17

US3742225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:29:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:34
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:08:47

US3742225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:29:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:34
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Temporomandibular joint surgery'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:08:47

US3742225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:29:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:34
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered 'Medical History (MH)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:08:47

US3742225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:29:59

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 20:04:34
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:02
User entered empty.	(b) (4)	17 Feb 2021 17:08:47
	(b) (4), (b) (6)	



US3742225

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:29:59**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered '14 Apr 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:35:26

US3742225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:29:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'SUBOCCIPITAL DECOMPRESSION'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:35:26

US3742225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:29:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:35:26

US3742225

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:29:59**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:35:26

US3742225

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:29:59**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered '14 Apr 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:36:43

US3742225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:29:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'PERICRANIAL GRAFT'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:36:43

US3742225

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:29:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:36:43

US3742225

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:29:59**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:36:43



**US3742225**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:29:59**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'USA-US127-2021-MRNA-1273-P301000017'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

Serious

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'Yes (Y)'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

Death

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'No (N)'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'No (N)'	System	29 Apr 2021 20:48:21

**US3742225**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:29:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'Yes (Y)'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'No (N)'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'No (N)'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'No (N)'	System	29 Apr 2021 20:48:21



US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'Karen'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'Kotloff'	System	29 Apr 2021 20:48:21

**US3742225**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:29:59**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered '685 W. Baltimore Street, HSF 480'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'Baltimore'	System	29 Apr 2021 20:48:21

**US3742225**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:29:59**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered '21201'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:28:43
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
User entered 'US'	(b) (4) System	29 Apr 2021 20:48:45

**US3742225**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:29:59**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	30 Apr 2021 18:23:33
User entered '2'	System	30 Apr 2021 17:28:59
User entered '1'	System	29 Apr 2021 20:48:45

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'USA-US127-2021-MRNA-1273-P301000017'	System	29 Apr 2021 20:48:21



US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

Serious

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'Yes (Y)'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

Death

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'No (N)'	System	29 Apr 2021 20:48:21

**US3742225**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:29:59**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'No (N)'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'Yes (Y)'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'No (N)'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'No (N)'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'No (N)'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'Karen'	System	29 Apr 2021 20:48:21



US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'Kotloff'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered '685 W. Baltimore Street, HSF 480'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'Baltimore'	System	29 Apr 2021 20:48:21

**US3742225**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:29:59**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered '21201'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:28:43
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
User entered 'US'	(b) (4) System	29 Apr 2021 20:48:45

**US3742225**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:29:59**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	30 Apr 2021 18:23:33
User entered '2'	System	30 Apr 2021 17:28:59
User entered '1'	System	29 Apr 2021 20:48:45

**US3742225**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000017**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:29:59**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
User entered '29/Apr/2021 15:48'	(b) (4) System	29 Apr 2021 20:48:45

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:29:59

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:28:43
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:45



US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'USA-US127-2021-MRNA-1273-P301000017'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

Serious

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'Yes (Y)'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

Death

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'No (N)'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'No (N)'	System	29 Apr 2021 20:48:21

**US3742225**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:29:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'Yes (Y)'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'No (N)'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'No (N)'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'No (N)'	System	29 Apr 2021 20:48:21



US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'Karen'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'Kotloff'	System	29 Apr 2021 20:48:21

**US3742225**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:29:59**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered '685 W. Baltimore Street, HSF 480'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'Baltimore'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered '21201'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:28:43
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
User entered 'US'	(b) (4) System	29 Apr 2021 20:48:45

**US3742225**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:29:59**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	30 Apr 2021 18:23:33
User entered '2'	System	30 Apr 2021 17:28:59
User entered '1'	System	29 Apr 2021 20:48:45

**US3742225**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000017**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:29:59**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 18:00:56
User entered '30/Apr/2021 10:28'	(b) (4) System	30 Apr 2021 17:28:59



US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:29:59

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 18:23:20
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 18:00:56
User entered 'I'	(b) (4), (b) (6)	30 Apr 2021 17:28:59

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'USA-US127-2021-MRNA-1273-P301000017'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

Serious

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'Yes (Y)'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

Death

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'No (N)'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'No (N)'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'Yes (Y)'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'No (N)'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'No (N)'	System	29 Apr 2021 20:48:21



US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'No (N)'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'Karen'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'Kotloff'	System	29 Apr 2021 20:48:21

**US3742225**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:29:59**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered '685 W. Baltimore Street, HSF 480'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered 'Baltimore'	System	29 Apr 2021 20:48:21

**US3742225**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:29:59**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:38
User entered '21201'	System	29 Apr 2021 20:48:21

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:29:59

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:28:43
User signature succeeded.	Milagritos Tapia (b) (4)	30 Apr 2021 13:31:17
User entered 'US'	(b) (4) System	29 Apr 2021 20:48:45

**US3742225**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:29:59**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	30 Apr 2021 18:23:33
User entered '2'	System	30 Apr 2021 17:28:59
User entered '1'	System	29 Apr 2021 20:48:45



**US3742225**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000017**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:29:59**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered '30/Apr/2021 11:23'	(b) (4) System	30 Apr 2021 18:23:33

US3742225

Folder: SAE USA-US127-2021-MRNA-1273-P301000017

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:29:59

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	01 May 2021 13:52:01
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:23:33