

US3422281 (Prod: Vanderbilt University Medical Center)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:34:58

All time stamps listed in this document are displayed in GMT

US3422281

Form: Participant Creation

Data signed: (b) (4) 01 Apr 2021 23:28:59

Generated On: 09 Jun 2021 17:34:58

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Participant ID

US3422281

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

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US3422281

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

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

US3422281

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Date of Birth (MMM yyyy)	(b) (6) 1955
Age	65
Age Units	YEARS
Age (Derived)	65
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) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Date of Informed Consent ( <i>dd MMM yyyy</i> )	15 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) 19 Feb 2021 20:54:54

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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) 19 Feb 2021 20:54:54

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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) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Condition	OSTEOARTHRITIS, GENERALIZED
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Condition	GERD
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Condition	MENOPAUSE
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Condition	MAGNESIUM DEFICIENCY
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Condition	CALCIUM DEFICIENCY
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	15 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	10:27 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 10:27
Height ( <i>xxx.x</i> )	65 in
Weight ( <i>xxx.x</i> )	150 lb
BMI ( <i>xxx.x</i> )	25.01350 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) 19 Feb 2021 20:54:54

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 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) 19 Feb 2021 20:54:54

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Date of assessment (*dd MMM yyyy*) 15 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*) UN UNK 2000

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 20:54:54

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

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**Specify**

FREQUENTLY IN CROWDED  
PUBLIC AREAS MULTIPLE  
TIMES PER WEEK

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

**No Risk Identified** False

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

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EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 20:54:54

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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)	True
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

What was the date of randomization? (dd MMM yyyy) 15 SEP 2020

What was the participant's randomization number? 190955

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) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

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) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

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)	15 SEP 2020
Time of assessment (00:00-23:59)	10:27 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 10:27
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

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)	15 SEP 2020
Time of assessment (00:00-23:59)	11:36 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 11:36
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

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: Exposure

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

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) 15 SEP 2020

What was the treatment time? (00:00-23:59) 11:06 (24 HR)

Treatment Date and Time (derived) 15 SEP 2020 11:06

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 SEP 2020

Collection time (00:00-23:59)

10:33 (24 HR)

Collection date and time (derived)

15 SEP 2020 10:33

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Collection date ( <i>dd MMM yyyy</i> )			15 SEP 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:38	15 SEP 2020 10:38
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

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: 09 Jun 2021 17:34:58

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 11:39

PC Open Date & Time

15 SEP 2020 11:26

PC Close Date & Time

15 SEP 2020 13:56

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

**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 97.0 °F

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

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

PC Time Stamp	15 SEP 2020 20:50
PC Open Date & Time	15 SEP 2020 14:51
PC Close Date & Time	16 SEP 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:58

**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

97.5 °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

16 SEP 2020 21:22

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:58

**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

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

18 SEP 2020 05:59

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 06:54

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 07:05

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 08:45

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 08:44

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 11:41

PC Open Date & Time

15 SEP 2020 11:26

PC Close Date & Time

15 SEP 2020 13:56

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

**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

15 SEP 2020 20:51

PC Open Date & Time

15 SEP 2020 14:51

PC Close Date & Time

16 SEP 2020 11:59



US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:58

**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

16 SEP 2020 21:23

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:58

**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

18 SEP 2020 05:59

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:58

**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

19 SEP 2020 06:55

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:58

**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

20 SEP 2020 07:05

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:58

**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

21 SEP 2020 08:45

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:58

**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

22 SEP 2020 08:44

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

**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 ☐

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

No ☒

Yes ☐

PC Time stamp	15 SEP 2020 11:42
PC Open Date & Time	15 SEP 2020 11:26
PC Close Date & Time	15 SEP 2020 13:56



US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

**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 ☐

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

No ☒

Yes ☐

PC Time stamp	15 SEP 2020 20:51
PC Open Date & Time	15 SEP 2020 14:51
PC Close Date & Time	16 SEP 2020 11:59

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:58

**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 ☒

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:58

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 21:23
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:58

**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 ☒

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:58

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 06:00
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:58

**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 ☒

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:58

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 06:55
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59



US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:58

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 ☒

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:58

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 07:06
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:58

**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 ☒

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:58

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 08:46
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:58

**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 ☒

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EAB) (1725)

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US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:58

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 08:45
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3422281

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3422281

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3422281

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3422281

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422281

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 6 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3422281

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422281

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

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 OCT 2020
Time of assessment (00:00-23:59)	09:58 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 09:58
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	075 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	014 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	065 mmHg
Diastolic Blood Pressure units	MMHG

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	14 OCT 2020
Time of assessment (00:00-23:59)	11:08 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 11:08
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	057 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	012 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	058 mmHg
Diastolic Blood Pressure units	MMHG

US3422281

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 OCT 2020

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



US3422281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

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) 14 OCT 2020

What was the treatment time? (00:00-23:59) 10:38 (24 HR)

Treatment Date and Time (derived) 14 OCT 2020 10:38

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

US3422281

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	14 OCT 2020
Collection time ( <i>00:00-23:59</i> )	10:05 (24 HR)
Collection date and time (derived)	14 OCT 2020 10:05

US3422281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Collection date (dd MMM yyyy)			14 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:03	14 OCT 2020 10:03
Nasopharyngeal Swab 2	No		

US3422281

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

**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

98.7 °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

14 OCT 2020 11:11

PC Open Date & Time

14 OCT 2020 10:58

PC Close Date & Time

14 OCT 2020 13:28

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

PC Time Stamp	14 OCT 2020 14:31
PC Open Date & Time	14 OCT 2020 14:23
PC Close Date & Time	15 OCT 2020 11:59

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:58

**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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 05:59

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:58

**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

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

17 OCT 2020 08:59

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59



US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

18 OCT 2020 07:46

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 09:58

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

20 OCT 2020 06:34

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

21 OCT 2020 06:24

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

**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

14 OCT 2020 11:11

PC Open Date & Time

14 OCT 2020 10:58

PC Close Date & Time

14 OCT 2020 13:28

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

**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

14 OCT 2020 14:31

PC Open Date & Time

14 OCT 2020 14:23

PC Close Date & Time

15 OCT 2020 11:59

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:58

**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

16 OCT 2020 05:59

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:58

**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

17 OCT 2020 09:00

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59



US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:58

**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

18 OCT 2020 07:46

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:58

**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

19 OCT 2020 09:59

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:58

**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

20 OCT 2020 06:35

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:58

**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

21 OCT 2020 06:25

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

**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 ☐

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

No ☒

Yes ☐

PC Time stamp	14 OCT 2020 11:12
PC Open Date & Time	14 OCT 2020 10:58
PC Close Date & Time	14 OCT 2020 13:28

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

**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 ☐

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

No ☒

Yes ☐

PC Time stamp	14 OCT 2020 14:32
PC Open Date & Time	14 OCT 2020 14:23
PC Close Date & Time	15 OCT 2020 11:59



US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:58

**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 ☒

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:58

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 06:00
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:58

**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 ☒

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:58

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 09:00
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:58

**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 ☒

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US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:58

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 07:46
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:58

**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 ☒

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:58

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



US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:58

**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 ☒

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:58

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 06:35
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:58

**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 ☒

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:58

Yes <input type="checkbox"/>	
PC Time stamp	21 OCT 2020 06:25
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3422281

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3422281

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422281

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3422281

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3422281

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3422281

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422281

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3422281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Mar 2021 13:47:37

Generated On: 09 Jun 2021 17:34:58

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) \_\_\_\_\_

US3422281

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

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.*

US3422281

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 NOV 2020

Collection time (00:00-23:59)

09:00 (24 HR)

Collection date and time (derived)

24 NOV 2020 09:00

US3422281

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:54:54

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422281

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

<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	15 NOV 2020 08:30:59
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59



US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT	DAY 68
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"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

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23 NOV 2020 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 06:45:11
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 DEC 2020 12:00:24

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 DEC 2020 07:12:38

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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	19 DEC 2020 12:00:35
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 DEC 2020 07:12:37

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	31 DEC 2020 06:36:10
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59



US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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

08 JAN 2021 08:46:30

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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	14 JAN 2021 06:35:32
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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

21 JAN 2021 06:37:44

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

<b>TIMEPOINT</b>	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 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 JAN 2021 11:43:25
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

<b>TIMEPOINT</b>	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 18:01:40
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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

11 FEB 2021 07:18:43

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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

18 FEB 2021 07:34:40

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 16:54:19

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59



US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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

04 MAR 2021 06:05:34

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 MAR 2021 09:04:10
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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

20 MAR 2021 12:11:07

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 06:12:49

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 09:04:42

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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

10 APR 2021 12:03:57

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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

18 APR 2021 18:00:24

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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

22 APR 2021 06:16:08

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59



US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 07:20:51

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 <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"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

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10 MAY 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

13 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 <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"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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20 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☐



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 MAY 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 JUN 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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10 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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14 JUN 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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17 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUN 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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"/>



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

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28 JUN 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

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05 JUL 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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="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"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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="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"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUL 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☐



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	22 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUL 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☐

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

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16 AUG 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

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23 AUG 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

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30 AUG 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☐

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

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06 SEP 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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°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 ☐

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

09 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☐



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

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20 SEP 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☐

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 SEP 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☐

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	30 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 OCT 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	07 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 OCT 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☐



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	14 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

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01 NOV 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

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08 NOV 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

11 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☐

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

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22 NOV 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

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

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 NOV 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 DEC 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 DEC 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

16 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☐

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 DEC 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☐

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

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

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



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

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10 JAN 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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="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"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JAN 2022 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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20 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 JAN 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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 <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"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

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31 JAN 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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°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 ☐



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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10 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 FEB 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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°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 ☐

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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17 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 FEB 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☐  
Yes ☐

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☐



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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03 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 MAR 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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10 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 MAR 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☐

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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17 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 MAR 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☐

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

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28 MAR 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☐



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

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04 APR 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☐

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

07 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☐

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	14 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 APR 2022 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☐

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 APR 2022 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☐



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

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16 MAY 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

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23 MAY 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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"/>



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

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30 MAY 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 JUN 2022 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

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20 JUN 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☐



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 JUN 2022 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

30 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

07 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☐ Yes ☐

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

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18 JUL 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☐



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

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25 JUL 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

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01 AUG 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

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08 AUG 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

11 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☐



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

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[Patient Cloud Close Date & Time](#)

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22 AUG 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☐

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	25 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2022 23:59
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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

01 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	08 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 SEP 2022 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 SEP 2022 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	22 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 SEP 2022 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 OCT 2022 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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 ☐

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	06 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 OCT 2022 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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"/>



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 OCT 2022 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2022 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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°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 ☐

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 OCT 2022 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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03 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 NOV 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**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°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 ☐



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 NOV 2022 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

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

17 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2022 23:59

US3422281

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:34:58

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		04 MAR 2021 06:05:43

US3422281

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:00:01

Generated On: 09 Jun 2021 17:34:58

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 DEC 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3422281

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:00:01

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422281

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3422281

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3422281

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3422281

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422281

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3422281

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422281

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3422281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

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) \_\_\_\_\_

US3422281

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

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.*

US3422281

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	29 MAR 2021
Collection time ( <i>00:00-23:59</i> )	09:05 (24 HR)
Collection date and time (derived)	29 MAR 2021 09:05



US3422281

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3422281**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:58**

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*

**US3422281**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:58**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3422281

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:34:58

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

**US3422281**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 17:34:58**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3422281

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

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

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

Visit date (dd MMM yyyy)	12 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3422281

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 03:01:02

Generated On: 09 Jun 2021 17:34:58

Date of updated informed consent ( <i>dd MMM yyyy</i> )	06 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> )	12 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

US3422281

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	



US3422281

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

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)	12 JAN 2021
Time of assessment (00:00-23:59)	08:52 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 08:52
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	086 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	014 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	071 mmHg
Diastolic Blood Pressure units	MMHG

US3422281

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

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)	12 JAN 2021
Time of assessment (00:00-23:59)	09:40 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 09:40
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	068 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	012 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	075 mmHg
Diastolic Blood Pressure units	MMHG

US3422281

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

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

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.*

US3422281

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

Form: Exposure

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

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) 12 JAN 2021

What was the treatment time? (00:00-23:59) 09:15 (24 HR)

Treatment Date and Time (derived) 12 JAN 2021 09:15

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

US3422281

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	12 JAN 2021
Collection time ( <i>00:00-23:59</i> )	08:54 (24 HR)
Collection date and time (derived)	12 JAN 2021 08:54

US3422281

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00 - 23:59)	08:57
Collection Date and Time (derived)	12 JAN 2021 08:57

US3422281

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

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422281

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Mar 2021 13:47:37

Generated On: 09 Jun 2021 17:34:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3422281

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Mar 2021 13:47:37

Generated On: 09 Jun 2021 17:34:58

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

US3422281

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

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

US3422281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

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 ( <i>dd MMM yyyy</i> )	08 FEB 2021
Time of assessment ( <i>00:00-23:59</i> )	10:40 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 10:40
Temperature ( <i>xxx.x</i> )	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	085 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	018 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	080 mmHg
Diastolic Blood Pressure units	MMHG

US3422281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

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)	08 FEB 2021
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 11:25
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	071 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	014 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	070 mmHg
Diastolic Blood Pressure units	MMHG

US3422281

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

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.*

US3422281

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

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) 08 FEB 2021

What was the treatment time? (00:00-23:59) 10:55 (24 HR)

Treatment Date and Time (derived) 08 FEB 2021 10:55

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

US3422281

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422281

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Mar 2021 13:47:37

Generated On: 09 Jun 2021 17:34:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3422281

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 28 Mar 2021 13:47:37

Generated On: 09 Jun 2021 17:34:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422281

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3422281

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	8 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	11:00 (24 HR)
Vital Signs Date and Time (derived)	8 MAR 2021 11:00
Temperature ( <i>xxx.x</i> )	097.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	067 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	055 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3422281

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

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.*

US3422281

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	8 MAR 2021
Collection time ( <i>00:00-23:59</i> )	11:01 (24 HR)
Collection date and time (derived)	8 MAR 2021 11:01

US3422281

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 18 Mar 2021 21:34:29

Generated On: 09 Jun 2021 17:34:58

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3422281

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 01 Apr 2021 23:28:59

Generated On: 09 Jun 2021 17:34:58

AEID	USA-US082-2020-MRNA-1273-P30 1000003
Adverse event	WORSENING OSTEOARTHRITIS
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)	27 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	28 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	27 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	28 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" 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) 01 Apr 2021 23:28:59

Generated On: 09 Jun 2021 17:34:58

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
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	PARTICIPANT SCHEDULED FOR ELECTIVE LEFT TOTAL KNEE ARTHROPLASTY SPENT ONE EVENING INPATIENT.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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EAB) (1725)



US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

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

Yes ☒

No ☐

---

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

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US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 15:38:11

Generated On: 09 Jun 2021 17:34:58

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication ACID REFLUX

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 15:38:11

Generated On: 09 Jun 2021 17:34:58

	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 2008	
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"/>

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 15:38:11

Generated On: 09 Jun 2021 17:34:58

Name of Medication MELOXICAM

Prophylaxis Yes ☐  
No ☒

Indication OSTEO-ARTHRITIS,  
GENERALIZED

Dose per administration 7.5

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 15:38:11

Generated On: 09 Jun 2021 17:34:58

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

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 15:38:11

Generated On: 09 Jun 2021 17:34:58

Name of Medication DILAUDID

Prophylaxis Yes ☐  
No ☒

Indication PAIN POST PROCEDURE

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 15:38:11

Generated On: 09 Jun 2021 17:34:58

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

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 15:38:11

Generated On: 09 Jun 2021 17:34:58

Name of Medication XARELTO

Prophylaxis Yes ☒  
No ☐

Indication BLOOD CLOT PREVENTION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 15:38:11

Generated On: 09 Jun 2021 17:34:58

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

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 15:38:11

Generated On: 09 Jun 2021 17:34:58

Name of Medication BIOTIN

Prophylaxis Yes ☒  
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 15:38:11

Generated On: 09 Jun 2021 17:34:58

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

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 15:38:11

Generated On: 09 Jun 2021 17:34:58

Name of Medication CALCIUM CARBONATE

Prophylaxis Yes ☐  
No ☒

Indication GERD (DUE TO OMEPRAZOLE USE), CALCIUM DEFICIENCY

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 15:38:11

Generated On: 09 Jun 2021 17:34:58

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 MAY 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 15:38:11

Generated On: 09 Jun 2021 17:34:58

Name of Medication MAGNESIUM CITRATE

Prophylaxis Yes ☐  
No ☒

Indication LAXATIVE, (PATIENT TOOK  
FOR MAGNESIUM DEFICIENCY,  
BUT DIDN'T MEAN TO GET THE  
LAXATIVE)

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 15:38:11

Generated On: 09 Jun 2021 17:34:58

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	05 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	05 NOV 2020	
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"/>

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 15:38:11

Generated On: 09 Jun 2021 17:34:58

Name of Medication SUPER C COMPLEX, VITAMIN C  
AND BIOFLAVINOIDS

Prophylaxis Yes ☒  
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 1000/500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 15:38:11

Generated On: 09 Jun 2021 17:34:58

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 15:38:11

Generated On: 09 Jun 2021 17:34:58

Name of Medication MAGNESIUM

Prophylaxis Yes ☐  
No ☒

Indication GERD (DUE TO OMEPRAZOLE  
USE), MAGNESIUM DEFICIENCY

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 15:38:11

Generated On: 09 Jun 2021 17:34:58

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 MAY 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3422281

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3422281

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
27 OCT 2020	PRIMARY LEFT TOTAL KNEE ARTHROPLASTY	Adverse Event	

US3422281

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:34:58

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

US3422281

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:34:58

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 ☐

US3422281

Folder: SAE USA-US082-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

SAEID	USA-US082-2020-MRNA-1273-P301000003
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	CLARENCE
Investigator's Last Name	CREECH
Site Address: Street	CCC-5311 MCN
Site Address: City	NASHVILLE
Site Address: State	TN
Site Address: Postal Code	37027
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7



US3422281

Folder: SAE USA-US082-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

SAEID	USA-US082-2020-MRNA-1273-P301000003
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	CLARENCE
Investigator's Last Name	CREECH
Site Address: Street	CCC-5311 MCN
Site Address: City	NASHVILLE
Site Address: State	TN
Site Address: Postal Code	37027
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	02/NOV/2020 20:43
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

US3422281

Folder: SAE USA-US082-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

SAEID	USA-US082-2020-MRNA-1273-P301000003
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	CLARENCE
Investigator's Last Name	CREECH
Site Address: Street	CCC-5311 MCN
Site Address: City	NASHVILLE
Site Address: State	TN
Site Address: Postal Code	37027
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	10/NOV/2020 09:48
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

US3422281

Folder: SAE USA-US082-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

SAEID	USA-US082-2020-MRNA-1273-P301000003
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	CLARENCE
Investigator's Last Name	CREECH
Site Address: Street	CCC-5311 MCN
Site Address: City	NASHVILLE
Site Address: State	TN
Site Address: Postal Code	37027
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	16/NOV/2020 21:11
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

US3422281

Folder: SAE USA-US082-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

SAEID	USA-US082-2020-MRNA-1273-P301000003
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	CLARENCE
Investigator's Last Name	CREECH
Site Address: Street	CCC-5311 MCN
Site Address: City	NASHVILLE
Site Address: State	TN
Site Address: Postal Code	37027
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	24/NOV/2020 16:08
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

US3422281

Folder: SAE USA-US082-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

SAEID	USA-US082-2020-MRNA-1273-P301000003
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	CLARENCE
Investigator's Last Name	CREECH
Site Address: Street	CCC-5311 MCN
Site Address: City	NASHVILLE
Site Address: State	TN
Site Address: Postal Code	37027
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	22/DEC/2020 16:02
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

US3422281

Folder: SAE USA-US082-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

SAEID	USA-US082-2020-MRNA-1273-P301000003
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	CLARENCE
Investigator's Last Name	CREECH
Site Address: Street	CCC-5311 MCN
Site Address: City	NASHVILLE
Site Address: State	TN
Site Address: Postal Code	37027
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	28/JAN/2021 12:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3422281

Folder: SAE USA-US082-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Data signed: (b) (4) 01 Apr 2021 23:29:00

Generated On: 09 Jun 2021 17:34:58

SAEID	USA-US082-2020-MRNA-1273-P301000003
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	CLARENCE
Investigator's Last Name	CREECH
Site Address: Street	CCC-5311 MCN
Site Address: City	NASHVILLE
Site Address: State	TN
Site Address: Postal Code	37027
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	22/MAR/2021 12:35
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

US3422281 (Prod: Vanderbilt University Medical Center)



**US3422281**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:34:58**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'US3422281'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 15:34:35

US3422281

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	15 Sep 2020 17:27:32

US3422281

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '15 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 15:34:36

US3422281

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

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 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Clinic (Clinic)'	Cindy Trimmer (b) (4)	15 Sep 2020 17:27:32

**US3422281**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered 'SCRN'	System	15 Sep 2020 17:27:32

US3422281

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:58

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered (b) (6) 1955'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 15:34:37

US3422281

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:58

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '65'	Cindy Trimmer (b) (4)	15 Sep 2020 17:27:50

US3422281

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:58

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered 'YEARS'	System	15 Sep 2020 17:27:50



US3422281

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:58

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered '65'	System	15 Sep 2020 16:08:40

**US3422281**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:34:58**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Female (F)'	Cindy Trimmer (b) (4)	15 Sep 2020 17:27:50

US3422281

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:58

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Cindy Trimmer (b) (4)	15 Sep 2020 17:27:50

US3422281

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:58

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'I'	Cindy Trimmer (b) (4)	15 Sep 2020 17:27:50

**US3422281**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:34:58**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	Cindy Trimmer (b) (4)	15 Sep 2020 17:27:50

**US3422281**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:34:58**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	Cindy Trimmer (b) (4)	15 Sep 2020 17:27:50

US3422281

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:58

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	Cindy Trimmer (b) (4)	15 Sep 2020 17:27:50

**US3422281**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:34:58**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	Cindy Trimmer (b) (4)	15 Sep 2020 17:27:50



**US3422281**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:34:58**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	Cindy Trimmer (b) (4)	15 Sep 2020 17:27:50

US3422281

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:58

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	(b) (4) Cindy Trimmer (b) (4)	15 Sep 2020 17:27:50

**US3422281**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:34:58**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	Cindy Trimmer (b) (4)	15 Sep 2020 17:27:50

US3422281

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:58

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	Cindy Trimmer (b) (4)	15 Sep 2020 17:27:50

US3422281

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:58

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 16:08:40

US3422281

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered 'Sep 2020'	System	15 Sep 2020 16:08:40

US3422281

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered '2020'	System	15 Sep 2020 16:08:40

**US3422281**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:34:58**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 16:08:40



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Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 16:08:40

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Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:58

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 16:08:40

US3422281

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:58

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 16:08:40

US3422281

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:58

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Sep 2020 16:08:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 16:08:40

US3422281

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:58

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User closed query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	(b) (4) System	15 Sep 2020 16:08:45
User opened query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	15 Sep 2020 16:08:40
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 15:34:36

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Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:58

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered 'I'	System	15 Sep 2020 16:08:40

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 16:08:17

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Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:34:58

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	15 Sep 2020 17:28:05



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Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid, Osteoarthritis, etc.) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 04:48:47
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Generalized osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:59:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:59:23
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid, Osteoarthritis, etc.) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'UPDATED' (Site from DM).	April Hanlotxomphou (b) (4)	28 Oct 2020 19:47:23
Data point term sent to Coder	System	28 Oct 2020 19:47:17
Coding entries removed.	April Hanlotxomphou (b) (4)	28 Oct 2020 19:47:13
User entered 'OSTEOARTHRITIS, GENERALIZED' reason for change: Data Entry Error	April Hanlotxomphou (b) (4)	28 Oct 2020 19:47:13
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid, Osteoarthritis, etc.) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 18:34:18
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:29:54

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EAB) (1725)

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Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	15 Sep 2020 17:29:54
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	15 Sep 2020 17:28:46
User entered 'Arthritis'	Cindy Trimmer (b) (4)	15 Sep 2020 17:28:21
	(b) (4)	

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Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'un UNK 2000' reason for change: New Information	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:47:21
User entered '30 Jun 2000'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:28:21

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Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	Cindy Trimmer (b) (4)	15 Sep 2020 17:28:21

**US3422281**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	15 Sep 2020 17:28:21

US3422281

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	Cindy Trimmer (b) (4)	15 Sep 2020 17:28:21

**US3422281**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	Cindy Trimmer (b) (4)	15 Sep 2020 17:28:21

**US3422281**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered 'Jan 2000'	System	14 Oct 2020 19:47:21
User entered 'Jun 2000'	System	15 Sep 2020 17:28:21



**US3422281**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered '2000'	System	15 Sep 2020 17:28:21

**US3422281**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered empty.	System	15 Sep 2020 17:28:21

**US3422281**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered empty.	System	15 Sep 2020 17:28:21

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 04:49:26
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'VERIFIED, DUE TO GENERALIZED OSTEOARTHRITIS' (Site from DM).	April Hanlotxomphou (b) (4)	28 Oct 2020 19:48:54
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 03:26:26
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:31:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:31:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:30:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:30:46
Data point term sent to Coder	System	15 Sep 2020 17:29:47
User entered 'R knee replacement'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:28:49

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'un May 2020' reason for change: New Information	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:48:16
User entered '15 May 2020'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:28:49

**US3422281**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:34:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	Cindy Trimmer (b) (4)	15 Sep 2020 17:28:49

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Cindy Trimmer (b) (4)	15 Sep 2020 17:29:05
User entered 'Yes (Y)'	(b) (4)	
	Cindy Trimmer (b) (4)	15 Sep 2020 17:28:49
	(b) (4)	

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'un May 2020' reason for change: New Information	(b) (4), (b) (6)	14 Oct 2020 19:48:16
User entered '15 May 2020' reason for change: Data Entry Error	Cindy Trimmer (b) (4)	15 Sep 2020 17:29:05
User entered empty.	Cindy Trimmer (b) (4)	15 Sep 2020 17:28:49



**US3422281**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:34:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	Cindy Trimmer (b) (4)	15 Sep 2020 17:28:49

**US3422281**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered 'May 2020'	System	15 Sep 2020 17:28:49

**US3422281**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered '2020'	System	15 Sep 2020 17:28:49

**US3422281**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered 'May 2020'	System	15 Sep 2020 17:29:05
User entered empty.	System	15 Sep 2020 17:28:49

US3422281

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered '2020'	System	15 Sep 2020 17:29:05
User entered empty.	System	15 Sep 2020 17:28:49

US3422281

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	15 Sep 2020 17:30:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:30:43
Data point term sent to Coder	System	15 Sep 2020 17:29:50
User entered 'GERD'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:29:20

US3422281

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'un UNK 2008' reason for change: New Information	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:48:53
User entered '30 Jun 2008'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:29:20

**US3422281**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:34:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	Cindy Trimmer (b) (4)	15 Sep 2020 17:29:20



**US3422281**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:34:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	15 Sep 2020 17:29:20

US3422281

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	Cindy Trimmer (b) (4)	15 Sep 2020 17:29:20

**US3422281**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:34:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	Cindy Trimmer (b) (4)	15 Sep 2020 17:29:20

**US3422281**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered 'Jan 2008'	System	14 Oct 2020 19:48:53
User entered 'Jun 2008'	System	15 Sep 2020 17:29:20

**US3422281**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered '2008'	System	15 Sep 2020 17:29:20

**US3422281**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered empty.	System	15 Sep 2020 17:29:20

**US3422281**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered empty.	System	15 Sep 2020 17:29:20

US3422281

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:34:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	29 Oct 2020 20:01:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 20:01:20
Data point term sent to Coder	System	28 Oct 2020 19:58:38
User entered 'menopause'	(b) (4), (b) (6)	28 Oct 2020 19:57:42



US3422281

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'un UNK 2000'	(b) (4), (b) (6)	28 Oct 2020 19:57:42

US3422281

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:34:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:57:42

**US3422281**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:34:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:57:42

US3422281

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:57:42

**US3422281**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:34:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:57:42

**US3422281**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered 'Jan 2000'	System	28 Oct 2020 19:57:42

**US3422281**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered '2000'	System	28 Oct 2020 19:57:42

**US3422281**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered empty.	System	28 Oct 2020 19:57:42



**US3422281**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered empty.	System	28 Oct 2020 19:57:42

US3422281

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:34:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Nov 2020 21:38:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 21:38:22
Data point term sent to Coder	System	23 Nov 2020 16:05:43
User entered 'Deep Vein Thrombosis'	(b) (4), (b) (6)	23 Nov 2020 16:05:35

US3422281

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:05:35

US3422281

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:34:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:05:35

US3422281

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:34:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:05:35

**US3422281**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:05:35

US3422281

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:34:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:05:35

**US3422281**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered 'Jan 2012'	System	23 Nov 2020 16:05:35



**US3422281**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered '2012'	System	23 Nov 2020 16:05:35

**US3422281**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered 'Jan 2012'	System	23 Nov 2020 16:05:35

**US3422281**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered '2012'	System	23 Nov 2020 16:05:35

US3422281

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:34:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolus - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	23 Nov 2020 21:38:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:38:19
Data point term sent to Coder	System	23 Nov 2020 16:06:48
User entered 'pulmonary embolus'	(b) (4), (b) (6)	23 Nov 2020 16:06:27

US3422281

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:06:27

US3422281

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:34:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:06:27

US3422281

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:34:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:06:27

US3422281

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:06:27



US3422281

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:34:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:06:27

**US3422281**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered 'Jan 2012'	System	23 Nov 2020 16:06:27

**US3422281**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered '2012'	System	23 Nov 2020 16:06:27

**US3422281**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered 'Jan 2012'	System	23 Nov 2020 16:06:27

**US3422281**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered '2012'	System	23 Nov 2020 16:06:27

US3422281

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:34:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Bone, calcium, magnesium and phosphorus metabolism disorders, HLT: Magnesium metabolism disorders, PT: Magnesium deficiency, LLT: Magnesium deficiency - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	08 Dec 2020 14:35:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Dec 2020 14:35:59
Data point term sent to Coder	System	08 Dec 2020 14:35:27
User entered 'Magnesium deficiency'	Anna Gallion (b) (4) (b) (4)	08 Dec 2020 14:34:33

US3422281

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	Anna Gallion (b) (4)	08 Dec 2020 14:34:33

US3422281

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:34:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'I'	Anna Gallion (b) (4)	08 Dec 2020 14:34:33



**US3422281**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:34:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	Anna Gallion (b) (4)	08 Dec 2020 14:34:33

US3422281

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	Anna Gallion (b) (4)	08 Dec 2020 14:34:33

**US3422281**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:34:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	Anna Gallion (b) (4)	08 Dec 2020 14:34:33

**US3422281**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered empty.	System	08 Dec 2020 14:34:33

**US3422281**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered empty.	System	08 Dec 2020 14:34:33

US3422281

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered empty.	System	08 Dec 2020 14:34:33

**US3422281**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered empty.	System	08 Dec 2020 14:34:33

US3422281

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:34:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Bone, calcium, magnesium and phosphorus metabolism disorders, HLT: Calcium metabolism disorders, PT: Calcium deficiency, LLT: Calcium deficiency - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	08 Dec 2020 14:35:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Dec 2020 14:35:59
Data point term sent to Coder	System	08 Dec 2020 14:35:27
User entered 'Calcium deficiency'	Anna Gallion (b) (4) (b) (4)	08 Dec 2020 14:34:51



US3422281

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	(b) (4) Anna Gallion (b) (4)	08 Dec 2020 14:34:51

US3422281

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:34:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'I'	Anna Gallion (b) (4)	08 Dec 2020 14:34:51

US3422281

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:34:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	Anna Gallion (b) (4)	08 Dec 2020 14:34:51

US3422281

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	Anna Gallion (b) (4)	08 Dec 2020 14:34:51

US3422281

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:34:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	Anna Gallion (b) (4)	08 Dec 2020 14:34:51

**US3422281**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered empty.	System	08 Dec 2020 14:34:51

**US3422281**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered empty.	System	08 Dec 2020 14:34:51

**US3422281**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered empty.	System	08 Dec 2020 14:34:51



**US3422281**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:34:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered empty.	System	08 Dec 2020 14:34:51

US3422281

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	(b) (4) Cindy Trimmer (b) (4)	15 Sep 2020 17:29:57

US3422281

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '15 Sep 2020'	Cindy Trimmer (b) (4)	15 Sep 2020 17:29:57

**US3422281**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:58**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '10:27'	Cindy Trimmer (b) (4)	15 Sep 2020 17:29:57

US3422281

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered '15 Sep 2020 10:27'	System	15 Sep 2020 17:29:57

US3422281

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '65' in	(b) (4)	
	Cindy Trimmer (b) (4)	15 Sep 2020 17:29:57
	(b) (4)	
DataPoint set to visible.	System	15 Sep 2020 16:08:40

US3422281

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '150' lb	(b) (4) Cindy Trimmer (b) (4)	15 Sep 2020 17:29:57
DataPoint set to visible.	(b) (4) System	15 Sep 2020 16:08:40

US3422281

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered '25.01350'	System	15 Sep 2020 17:29:57
DataPoint set to visible.	System	15 Sep 2020 16:08:40



US3422281

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered 'kg/m2'	System	15 Sep 2020 17:29:57
DataPoint set to visible.	System	15 Sep 2020 16:08:40

US3422281

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 12:55:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 18:29:04
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 19:54:10
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:54:05
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 19:54:05
User entered '98.5' F	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:29:57

US3422281

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty; reason for change Data Entry Error	(b) (4)	
	Cindy Trimmer (b) (4)	21 Sep 2020 19:54:05
User entered 'Oral (Oral)'	(b) (4)	
	Cindy Trimmer (b) (4)	15 Sep 2020 17:29:57
	(b) (4)	

US3422281

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	(b) (4) Cindy Trimmer (b) (4)	15 Sep 2020 17:29:57

US3422281

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 12:55:14
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 18:29:04
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 19:54:15
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:54:05
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 19:54:05
User entered '78'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:29:57

US3422281

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered 'bpm'	System	25 Sep 2020 18:29:04
User entered empty.	System	21 Sep 2020 19:54:05
User entered 'bpm'	System	15 Sep 2020 17:29:57

US3422281

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 12:55:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 18:29:04
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 19:54:18
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:54:05
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 19:54:05
User entered '14'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:29:57

US3422281

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered 'breaths/min'	System	25 Sep 2020 18:29:04
User entered empty.	System	21 Sep 2020 19:54:05
User entered 'breaths/min'	System	15 Sep 2020 17:29:57



US3422281

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 12:55:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 18:29:04
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 19:54:21
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:54:05
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 19:54:05
User entered '149'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:29:57

US3422281

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered 'mmHg'	System	25 Sep 2020 18:29:04
User entered empty.	System	21 Sep 2020 19:54:05
User entered 'mmHg'	System	15 Sep 2020 17:29:57

US3422281

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 12:55:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 18:29:04
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 19:54:24
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:54:05
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 19:54:05
User entered '72'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:29:57

US3422281

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User entered 'mmHg'	System	25 Sep 2020 18:29:04
User entered empty.	System	21 Sep 2020 19:54:05
User entered 'mmHg'	System	15 Sep 2020 17:29:57

US3422281

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34

US3422281

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	15 Sep 2020 17:30:14

**US3422281**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:34:58**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '15 Sep 2020'	Cindy Trimmer (b) (4)	15 Sep 2020 17:30:14



US3422281

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:34:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '15 Sep 2020'	Cindy Trimmer (b) (4)	15 Sep 2020 17:56:47

US3422281

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:34:58

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'No (N)'	Cindy Trimmer (b) (4)	15 Sep 2020 17:56:47

US3422281

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:34:58

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 04:48:01
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'UPDATED' (Site from DM).	April Hanlotxomphou (b) (4)	28 Oct 2020 19:45:55
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 06:43:00
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:56:47

US3422281

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:34:58

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	Cindy Trimmer (b) (4)	15 Sep 2020 17:56:47

US3422281

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	Cindy Trimmer (b) (4)	15 Sep 2020 17:56:47

US3422281

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:34:58

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	Cindy Trimmer (b) (4)	15 Sep 2020 17:56:47

US3422281

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:34:58

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'un UNK 2000' reason for change: New Information	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:51:40
User entered '30 Jun 2000'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:56:47

US3422281

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:34:58

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	Cindy Trimmer (b) (4)	15 Sep 2020 17:56:47



US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

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 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'No (N)'	Cindy Trimmer (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

**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 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'No (N)'	Cindy Trimmer (b) (4)	15 Sep 2020 17:59:43

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Folder: Screening

Form: Risk of Exposure

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**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 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'No (N)'	Cindy Trimmer (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

**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 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'No (N)'	Cindy Trimmer (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

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[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 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'No (N)'	Cindy Trimmer (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

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[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 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'No (N)'	Cindy Trimmer (b) (4)	15 Sep 2020 17:59:43

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Folder: Screening

Form: Risk of Exposure

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**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 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'No (N)'	Cindy Trimmer (b) (4)	15 Sep 2020 17:59:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

**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 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'No (N)'	Cindy Trimmer (b) (4)	15 Sep 2020 17:59:43



US3422281

Folder: Screening

Form: Risk of Exposure

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[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 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'No (N)'	Cindy Trimmer (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

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**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 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'No (N)'	Cindy Trimmer (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

**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 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'No (N)'	Cindy Trimmer (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'frequently in crowded public areas multiple times per week'	Cindy Trimmer (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	Cindy Trimmer (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	Cindy Trimmer (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

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**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 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	Cindy Trimmer (b) (4)	15 Sep 2020 17:59:43



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[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 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	Cindy Trimmer (b) (4)	15 Sep 2020 17:59:43

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Folder: Screening

Form: Risk of Exposure

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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 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	Cindy Trimmer (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'I'	Cindy Trimmer (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '0'	Cindy Trimmer (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:58

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:23:34
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	Cindy Trimmer (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	15 Sep 2020 17:32:27

US3422281

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '15 Sep 2020'	(b) (4) Cindy Trimmer (b) (4)	15 Sep 2020 17:32:27

US3422281

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Clinic (Clinic)'	Cindy Trimmer (b) (4)	15 Sep 2020 17:32:27



US3422281

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'VISIT1'	System	15 Sep 2020 17:32:27

US3422281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '15 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 15:39:49

US3422281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:58

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '190955'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 15:39:49

US3422281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:58

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 15:39:49

US3422281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:58

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 16:09:03

US3422281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:58

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 16:09:03

US3422281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:58

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 16:09:03

US3422281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:58

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 16:09:03



US3422281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:58

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 16:09:03

US3422281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:58

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'No (N)'	(b) (4) Cindy Trimmer (b) (4)	21 Sep 2020 19:54:30
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 09:15:22
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:15:21

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 18:28:50
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4)	21 Sep 2020 19:54:41
User entered '65' in	(b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 18:28:50
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4)	21 Sep 2020 19:54:41
User entered '150' lb	(b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 18:28:50
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4)	21 Sep 2020 19:54:41
User entered '65' in	(b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 18:28:50
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4)	21 Sep 2020 19:54:41
User entered '150' lb	(b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User accepted default value 'Pre-Dose (PREDOSE)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:19



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '15 Sep 2020'	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '10:27'	(b) (4) Cindy Trimmer (b) (4)	15 Sep 2020 18:01:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered '15 Sep 2020 10:27'	System	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '98.5' F	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Oral (Oral)'	(b) (4) Cindy Trimmer (b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	(b) (4) Cindy Trimmer (b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '78'	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'bpm'	System	15 Sep 2020 18:01:19



US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '14'	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'breaths/min'	System	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '149'	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'mmHg'	System	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '72'	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'mmHg'	System	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 18:28:50
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4)	21 Sep 2020 19:54:41
User entered '65' in	(b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:58

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 18:28:50
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4)	21 Sep 2020 19:54:41
User entered '150' lb	(b) (4)	15 Sep 2020 18:01:19



US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User accepted default value 'Post-Dose (POSTDOSE)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '15 Sep 2020'	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '11:36'	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered '15 Sep 2020 11:36'	System	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '97.2' F	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Oral (Oral)'	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	(b) (4) Cindy Trimmer (b) (4)	15 Sep 2020 18:01:19



US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '63'	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'bpm'	System	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '14'	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'breaths/min'	System	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '140'	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'mmHg'	System	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '66'	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'mmHg'	System	15 Sep 2020 18:01:19



US3422281

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'No (N)'	Cindy Trimmer (b) (4)	15 Sep 2020 17:32:34

US3422281

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:58

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	Cindy Trimmer (b) (4)	15 Sep 2020 17:32:34

US3422281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 16:09:26

US3422281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 16:09:26

US3422281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 16:09:26

US3422281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'MRNA-1273 OR PLACEBO'	System	15 Sep 2020 16:09:26

US3422281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 16:09:26

US3422281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '11:06'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 16:09:26



US3422281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered '15 Sep 2020 11:06'	System	15 Sep 2020 16:09:26

US3422281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 16:09:26

US3422281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'ONCE'	System	15 Sep 2020 16:09:26

US3422281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'INTRAMUSCULAR'	System	15 Sep 2020 16:09:26

US3422281

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	(b) (4) Cindy Trimmer (b) (4)	15 Sep 2020 18:01:37

US3422281

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '15 Sep 2020'	(b) (4) Cindy Trimmer (b) (4)	15 Sep 2020 18:01:37

US3422281

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '10:33'	(b) (4) Cindy Trimmer (b) (4)	15 Sep 2020 18:01:37

US3422281

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered '15 Sep 2020 10:33'	System	15 Sep 2020 18:01:37



US3422281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:34:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '15 Sep 2020'	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:48

US3422281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:01:48

US3422281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:48

US3422281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '10:38'	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:48

US3422281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:58

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered '15 Sep 2020 10:38'	System	15 Sep 2020 18:01:48

US3422281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:01:48

US3422281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'No (N)'	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:48

US3422281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:48



US3422281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:58

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered empty.	System	15 Sep 2020 18:01:48

US3422281

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:54

**US3422281**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'I'	System	15 Sep 2020 18:01:54

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	15 Sep 2020 16:09:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T11:38:57', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'b355ef68-e350-422f-b012-fda51f698d0e' User entered 'Yes (Y)'	System	15 Sep 2020 16:39:27
	System	15 Sep 2020 16:39:27

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T11:39:04', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'b355ef68-e350-422f-b012-fda51f698d0e' User entered '97.2'	System	15 Sep 2020 16:39:27
	System	15 Sep 2020 16:39:27

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T11:39:13', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'b355ef68-e350-422f-b012-fda51f698d0e' User entered 'No (N)'	System	15 Sep 2020 16:39:27
	System	15 Sep 2020 16:39:27

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T11:39:23', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'b355ef68-e350-422f-b012-fda51f698d0e' User entered '15 Sep 2020 11:39'	System	15 Sep 2020 16:39:27
	System	15 Sep 2020 16:39:27



US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '15 Sep 2020 11:26'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '15 Sep 2020 13:56'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	15 Sep 2020 16:09:26
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T20:50:13', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'f1998b9d-6bc5-4f45-9193-cb7afba3a42c' User entered 'Yes (Y)'	System	16 Sep 2020 01:50:39
	System	16 Sep 2020 01:50:39

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T20:50:19', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'f1998b9d-6bc5-4f45-9193-cb7afba3a42c' User entered '97.0'	System	16 Sep 2020 01:50:39
	System	16 Sep 2020 01:50:39

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T20:50:24', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'f1998b9d-6bc5-4f45-9193-cb7afba3a42c' User entered 'No (N)'	System	16 Sep 2020 01:50:39
	System	16 Sep 2020 01:50:39

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T20:50:35', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'f1998b9d-6bc5-4f45-9193-cb7afba3a42c' User entered '15 Sep 2020 20:50'	System	16 Sep 2020 01:50:39
	System	16 Sep 2020 01:50:39

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '15 Sep 2020 14:51'	System	15 Sep 2020 16:09:26



US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	15 Sep 2020 16:09:26
User entered 'Day 2'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-16T21:22:33', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '14168a94-f2aa-4eff-9d31-bc794356069b' User entered 'Yes (Y)'	System	17 Sep 2020 02:22:53
	System	17 Sep 2020 02:22:53

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-16T21:22:42', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '14168a94-f2aa-4eff-9d31-bc794356069b' User entered '97.5'	System	17 Sep 2020 02:22:53
	System	17 Sep 2020 02:22:53

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-16T21:22:45', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '14168a94-f2aa-4eff-9d31-bc794356069b' User entered 'No (N)'	System	17 Sep 2020 02:22:53
	System	17 Sep 2020 02:22:53

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-16T21:22:50', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '14168a94-f2aa-4eff-9d31-bc794356069b' User entered '16 Sep 2020 21:22'	System	17 Sep 2020 02:22:53
	System	17 Sep 2020 02:22:53

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 16:09:26



US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	15 Sep 2020 16:09:26
User entered 'Day 3'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-18T05:58:58', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '4d6e1dbf-1b67-4a9c-a4eb-56c99dd95842' User entered 'Yes (Y)'	System	18 Sep 2020 10:59:51
	System	18 Sep 2020 10:59:51

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-18T05:59:08', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '4d6e1dbf-1b67-4a9c-a4eb-56c99dd95842' User entered '97.8'	System	18 Sep 2020 10:59:51
	System	18 Sep 2020 10:59:51

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-18T05:59:12', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '4d6e1dbf-1b67-4a9c-a4eb-56c99dd95842'	System	18 Sep 2020 10:59:51
User entered 'No (N)'	System	18 Sep 2020 10:59:51

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:34:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-18T05:59:20', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '4d6e1dbf-1b67-4a9c-a4eb-56c99dd95842' User entered '18 Sep 2020 05:59'	System	18 Sep 2020 10:59:51
	System	18 Sep 2020 10:59:51

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	15 Sep 2020 16:09:26
User entered 'Day 4'	System	15 Sep 2020 16:09:26



US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-19T06:54:33', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'adb605a7-9670-411d-988e-dad9e58d9fa1' User entered 'Yes (Y)'	System	19 Sep 2020 11:54:56
	System	19 Sep 2020 11:54:56

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-19T06:54:43', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'adb605a7-9670-411d-988e-dad9e58d9fa1' User entered '97.5'	System	19 Sep 2020 11:54:56
	System	19 Sep 2020 11:54:56

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-19T06:54:46', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'adb605a7-9670-411d-988e-dad9e58d9fa1' User entered 'No (N)'	System	19 Sep 2020 11:54:56
	System	19 Sep 2020 11:54:56

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:34:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-19T06:54:53', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'adb605a7-9670-411d-988e-dad9e58d9fa1' User entered '19 Sep 2020 06:54'	System	19 Sep 2020 11:54:56
	System	19 Sep 2020 11:54:56

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	15 Sep 2020 16:09:26
User entered 'Day 5'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-20T07:05:20', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '76768eae-087c-4a6b-9ffb-c5cae6f00ffa'	System	20 Sep 2020 12:05:39
User entered 'Yes (Y)'	System	20 Sep 2020 12:05:39



US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-20T07:05:28', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '76768eae-087c-4a6b-9ffb-c5cae6f00ffa' User entered '98.5'	System	20 Sep 2020 12:05:39
	System	20 Sep 2020 12:05:39

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-20T07:05:31', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '76768eae-087c-4a6b-9ffb-c5cae6f00ffa'	System	20 Sep 2020 12:05:39
User entered 'No (N)'	System	20 Sep 2020 12:05:39

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:34:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-20T07:05:34', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '76768eae-087c-4a6b-9ffb-c5cae6f00ffa'	System	20 Sep 2020 12:05:39
User entered '20 Sep 2020 07:05'	System	20 Sep 2020 12:05:39

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	15 Sep 2020 16:09:26
User entered 'Day 6'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-21T08:45:19', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '1512bce3-90a0-4214-b565-ebfc3e03455e' User entered 'Yes (Y)'	System	21 Sep 2020 13:45:37
	System	21 Sep 2020 13:45:37

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-21T08:45:26', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '1512bce3-90a0-4214-b565-ebfc3e03455e' User entered '97.6'	System	21 Sep 2020 13:45:37
	System	21 Sep 2020 13:45:37



US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-21T08:45:29', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '1512bce3-90a0-4214-b565-ebfc3e03455e' User entered 'No (N)'	System	21 Sep 2020 13:45:37
	System	21 Sep 2020 13:45:37

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:34:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-21T08:45:33', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '1512bce3-90a0-4214-b565-ebfc3e03455e' User entered '21 Sep 2020 08:45'	System	21 Sep 2020 13:45:37
	System	21 Sep 2020 13:45:37

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	15 Sep 2020 16:09:26
User entered 'Day 7'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-22T08:44:07', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '49d15c97-5b66-44c2-845d-fd3367fcc8a8' User entered 'Yes (Y)'	System	22 Sep 2020 13:44:26
	System	22 Sep 2020 13:44:26

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-22T08:44:15', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '49d15c97-5b66-44c2-845d-fd3367fcc8a8' User entered '98.2'	System	22 Sep 2020 13:44:26
	System	22 Sep 2020 13:44:26

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-22T08:44:19', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '49d15c97-5b66-44c2-845d-fd3367fcc8a8' User entered 'No (N)'	System	22 Sep 2020 13:44:26
	System	22 Sep 2020 13:44:26



**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:34:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-22T08:44:24', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '49d15c97-5b66-44c2-845d-fd3367fcc8a8' User entered '22 Sep 2020 08:44'	System	22 Sep 2020 13:44:26
	System	22 Sep 2020 13:44:26

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	15 Sep 2020 16:09:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T11:39:50', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'a6b84103-2691-4605-a311-2464084369cd' User entered 'None (1)'	System	15 Sep 2020 16:41:30
	System	15 Sep 2020 16:41:30

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T11:40:51', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'a6b84103-2691-4605-a311-2464084369cd' User entered 'No (N)'	System	15 Sep 2020 16:41:30
	System	15 Sep 2020 16:41:30

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T11:41:01', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'a6b84103-2691-4605-a311-2464084369cd' User entered 'No (N)'	System	15 Sep 2020 16:41:30
	System	15 Sep 2020 16:41:30

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T11:41:20', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'a6b84103-2691-4605-a311-2464084369cd' User entered 'None (1)'	System	15 Sep 2020 16:41:30
	System	15 Sep 2020 16:41:30



US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T11:41:29', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'a6b84103-2691-4605-a311-2464084369cd' User entered '15 Sep 2020 11:41'	System	15 Sep 2020 16:41:30
	System	15 Sep 2020 16:41:30

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '15 Sep 2020 11:26'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '15 Sep 2020 13:56'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	15 Sep 2020 16:09:26
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T20:50:52', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '3ec15c68-0f8f-4dc3-86ba-0fa1bd6522ea' User entered 'None (1)'	System	16 Sep 2020 01:51:10
	System	16 Sep 2020 01:51:10

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T20:50:55', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '3ec15c68-0f8f-4dc3-86ba-0fa1bd6522ea' User entered 'No (N)'	System	16 Sep 2020 01:51:10
	System	16 Sep 2020 01:51:10

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T20:50:58', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '3ec15c68-0f8f-4dc3-86ba-0fa1bd6522ea' User entered 'No (N)'	System	16 Sep 2020 01:51:10
	System	16 Sep 2020 01:51:10

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T20:51:02', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '3ec15c68-0f8f-4dc3-86ba-0fa1bd6522ea' User entered 'None (1)'	System	16 Sep 2020 01:51:10
	System	16 Sep 2020 01:51:10



US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T20:51:08', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '3ec15c68-0f8f-4dc3-86ba-0fa1bd6522ea' User entered '15 Sep 2020 20:51'	System	16 Sep 2020 01:51:10
	System	16 Sep 2020 01:51:10

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '15 Sep 2020 14:51'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	15 Sep 2020 16:09:26
User entered 'Day 2'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-16T21:22:56', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'cac01cb7-e01c-4d0f-b50f-f0246986cf6d'	System	17 Sep 2020 02:23:11
User entered 'None (1)'	System	17 Sep 2020 02:23:11

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-16T21:22:59', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'cac01cb7-e01c-4d0f-b50f-f0246986cf6d' User entered 'No (N)'	System	17 Sep 2020 02:23:11
	System	17 Sep 2020 02:23:11

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-16T21:23:02', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'cac01cb7-e01c-4d0f-b50f-f0246986cf6d' User entered 'No (N)'	System	17 Sep 2020 02:23:11
	System	17 Sep 2020 02:23:11

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-16T21:23:05', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'cac01cb7-e01c-4d0f-b50f-f0246986cf6d' User entered 'None (1)'	System	17 Sep 2020 02:23:11
	System	17 Sep 2020 02:23:11



**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:34:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-16T21:23:08', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'cac01cb7-e01c-4d0f-b50f-f0246986cf6d' User entered '16 Sep 2020 21:23'	System	17 Sep 2020 02:23:11
	System	17 Sep 2020 02:23:11

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	15 Sep 2020 16:09:26
User entered 'Day 3'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-18T05:59:25', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '5479a38d-6e76-4762-991e-6ab0abafd713' User entered 'None (1)'	System	18 Sep 2020 10:59:55
	System	18 Sep 2020 10:59:55

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-18T05:59:29', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '5479a38d-6e76-4762-991e-6ab0abafd713' User entered 'No (N)'	System	18 Sep 2020 10:59:55
	System	18 Sep 2020 10:59:55

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-18T05:59:31', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '5479a38d-6e76-4762-991e-6ab0abafd713' User entered 'No (N)'	System	18 Sep 2020 10:59:55
	System	18 Sep 2020 10:59:55

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-18T05:59:36', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '5479a38d-6e76-4762-991e-6ab0abafd713' User entered 'None (1)'	System	18 Sep 2020 10:59:55
	System	18 Sep 2020 10:59:55



US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-18T05:59:41', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '5479a38d-6e76-4762-991e-6ab0abafd713' User entered '18 Sep 2020 05:59'	System	18 Sep 2020 10:59:55
	System	18 Sep 2020 10:59:55

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	15 Sep 2020 16:09:26
User entered 'Day 4'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-19T06:54:57', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '1e61ceb7-e41d-4ecb-9deb-d8b5af76b19b' User entered 'None (1)'	System	19 Sep 2020 11:55:13
	System	19 Sep 2020 11:55:13

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-19T06:55:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '1e61ceb7-e41d-4ecb-9deb-d8b5af76b19b' User entered 'No (N)'	System	19 Sep 2020 11:55:13
	System	19 Sep 2020 11:55:13

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-19T06:55:03', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '1e61ceb7-e41d-4ecb-9deb-d8b5af76b19b' User entered 'No (N)'	System	19 Sep 2020 11:55:13
	System	19 Sep 2020 11:55:13

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-19T06:55:07', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '1e61ceb7-e41d-4ecb-9deb-d8b5af76b19b' User entered 'None (1)'	System	19 Sep 2020 11:55:13
	System	19 Sep 2020 11:55:13



US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-19T06:55:11', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '1e61ceb7-e41d-4ecb-9deb-d8b5af76b19b' User entered '19 Sep 2020 06:55'	System	19 Sep 2020 11:55:13
	System	19 Sep 2020 11:55:13

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	15 Sep 2020 16:09:26
User entered 'Day 5'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-20T07:05:38', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'e6fab16d-adc8-4e35-b7a3-54b7bf320648'	System	20 Sep 2020 12:06:00
User entered 'None (1)'	System	20 Sep 2020 12:06:00

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-20T07:05:44', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'e6fab16d-adc8-4e35-b7a3-54b7bf320648' User entered 'No (N)'	System	20 Sep 2020 12:06:00
	System	20 Sep 2020 12:06:00

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-20T07:05:49', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'e6fab16d-adc8-4e35-b7a3-54b7bf320648' User entered 'No (N)'	System	20 Sep 2020 12:06:00
	System	20 Sep 2020 12:06:00

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-20T07:05:54', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'e6fab16d-adc8-4e35-b7a3-54b7bf320648'	System	20 Sep 2020 12:06:00
User entered 'None (1)'	System	20 Sep 2020 12:06:00



**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:34:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-20T07:05:59', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'e6fab16d-adc8-4e35-b7a3-54b7bf320648' User entered '20 Sep 2020 07:05'	System	20 Sep 2020 12:06:00
	System	20 Sep 2020 12:06:00

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	15 Sep 2020 16:09:26
User entered 'Day 6'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-21T08:45:36', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '650fafc4-e947-48f4-9e4b-bb3860e36c4a' User entered 'None (1)'	System	21 Sep 2020 13:45:53
	System	21 Sep 2020 13:45:53

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-21T08:45:39', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '650fafc4-e947-48f4-9e4b-bb3860e36c4a' User entered 'No (N)'	System	21 Sep 2020 13:45:53
	System	21 Sep 2020 13:45:53

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-21T08:45:41', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '650fafc4-e947-48f4-9e4b-bb3860e36c4a' User entered 'No (N)'	System	21 Sep 2020 13:45:53
	System	21 Sep 2020 13:45:53

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-21T08:45:44', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '650fafc4-e947-48f4-9e4b-bb3860e36c4a' User entered 'None (1)'	System	21 Sep 2020 13:45:53
	System	21 Sep 2020 13:45:53



US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-21T08:45:48', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '650fafc4-e947-48f4-9e4b-bb3860e36c4a' User entered '21 Sep 2020 08:45'	System	21 Sep 2020 13:45:53
	System	21 Sep 2020 13:45:53

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	15 Sep 2020 16:09:26
User entered 'Day 7'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-22T08:44:32', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '80b0794b-12db-43fa-8543-f70951a0e130'	System	22 Sep 2020 13:44:47
User entered 'None (1)'	System	22 Sep 2020 13:44:47

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-22T08:44:35', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '80b0794b-12db-43fa-8543-f70951a0e130'	System	22 Sep 2020 13:44:47
User entered 'No (N)'	System	22 Sep 2020 13:44:47

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-22T08:44:37', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '80b0794b-12db-43fa-8543-f70951a0e130' User entered 'No (N)'	System	22 Sep 2020 13:44:47
	System	22 Sep 2020 13:44:47

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-22T08:44:40', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '80b0794b-12db-43fa-8543-f70951a0e130'	System	22 Sep 2020 13:44:47
User entered 'None (1)'	System	22 Sep 2020 13:44:47



US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-22T08:44:42', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '80b0794b-12db-43fa-8543-f70951a0e130' User entered '22 Sep 2020 08:44'	System	22 Sep 2020 13:44:47
	System	22 Sep 2020 13:44:47

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	15 Sep 2020 16:09:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T11:41:42', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'e0a1ffd0-9fe2-4d8c-8ed0-9bfc5c4a7c2f' User entered 'None (0)'	System	15 Sep 2020 16:42:30
	System	15 Sep 2020 16:42:30

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T11:41:48', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'e0a1ffd0-9fe2-4d8c-8ed0-9bfc5c4a7c2f' User entered 'None (0)'	System	15 Sep 2020 16:42:30
	System	15 Sep 2020 16:42:30

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T11:41:54', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'e0a1ffd0-9fe2-4d8c-8ed0-9bfc5c4a7c2f' User entered 'None (0)'	System	15 Sep 2020 16:42:30
	System	15 Sep 2020 16:42:30

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T11:42:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'e0a1ffd0-9fe2-4d8c-8ed0-9bfc5c4a7c2f' User entered 'None (0)'	System	15 Sep 2020 16:42:30
	System	15 Sep 2020 16:42:30



US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T11:42:04', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'e0a1ffd0-9fe2-4d8c-8ed0-9bfc5c4a7c2f' User entered 'None (0)'	System	15 Sep 2020 16:42:30
	System	15 Sep 2020 16:42:30

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T11:42:08', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'e0a1ffd0-9fe2-4d8c-8ed0-9bfc5c4a7c2f' User entered 'None (0)'	System	15 Sep 2020 16:42:30
	System	15 Sep 2020 16:42:30

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T11:42:14', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'e0a1ffd0-9fe2-4d8c-8ed0-9bfc5c4a7c2f' User entered 'No (N)'	System	15 Sep 2020 16:42:30
	System	15 Sep 2020 16:42:30

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T11:42:25', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'e0a1ffd0-9fe2-4d8c-8ed0-9bfc5c4a7c2f' User entered '15 Sep 2020 11:42'	System	15 Sep 2020 16:42:30
	System	15 Sep 2020 16:42:30

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '15 Sep 2020 11:26'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '15 Sep 2020 13:56'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	15 Sep 2020 16:09:26
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T20:51:13', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0dbe56bb-da0f-4a7c-842f-66d42b47ede6' User entered 'None (0)'	System	16 Sep 2020 01:51:38
	System	16 Sep 2020 01:51:38



US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T20:51:15', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0dbe56bb-da0f-4a7c-842f-66d42b47ede6' User entered 'None (0)'	System	16 Sep 2020 01:51:38
	System	16 Sep 2020 01:51:38

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T20:51:18', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0dbe56bb-da0f-4a7c-842f-66d42b47ede6' User entered 'None (0)'	System	16 Sep 2020 01:51:38
	System	16 Sep 2020 01:51:38

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T20:51:21', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0dbe56bb-da0f-4a7c-842f-66d42b47ede6' User entered 'None (0)'	System	16 Sep 2020 01:51:38
	System	16 Sep 2020 01:51:38

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T20:51:24', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0dbe56bb-da0f-4a7c-842f-66d42b47ede6' User entered 'None (0)'	System	16 Sep 2020 01:51:38
	System	16 Sep 2020 01:51:38

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T20:51:26', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0dbe56bb-da0f-4a7c-842f-66d42b47ede6' User entered 'None (0)'	System	16 Sep 2020 01:51:38
	System	16 Sep 2020 01:51:38

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T20:51:29', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0dbe56bb-da0f-4a7c-842f-66d42b47ede6' User entered 'No (N)'	System	16 Sep 2020 01:51:38
	System	16 Sep 2020 01:51:38

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:34:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-15T20:51:33', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0dbe56bb-da0f-4a7c-842f-66d42b47ede6' User entered '15 Sep 2020 20:51'	System	16 Sep 2020 01:51:38
	System	16 Sep 2020 01:51:38

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '15 Sep 2020 14:51'	System	15 Sep 2020 16:09:26



US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	15 Sep 2020 16:09:26
User entered 'Day 2'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-16T21:23:13', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'bec9a10c-51a3-420a-ac93-87bcc60aff1f' User entered 'None (0)'	System	17 Sep 2020 02:23:31
	System	17 Sep 2020 02:23:31

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-16T21:23:15', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'bec9a10c-51a3-420a-ac93-87bcc60aff1f' User entered 'None (0)'	System	17 Sep 2020 02:23:31
	System	17 Sep 2020 02:23:31

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-16T21:23:17', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'bec9a10c-51a3-420a-ac93-87bcc60aff1f' User entered 'None (0)'	System	17 Sep 2020 02:23:31
	System	17 Sep 2020 02:23:31

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-16T21:23:19', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'bec9a10c-51a3-420a-ac93-87bcc60aff1f' User entered 'None (0)'	System	17 Sep 2020 02:23:31
	System	17 Sep 2020 02:23:31

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-16T21:23:21', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'bec9a10c-51a3-420a-ac93-87bcc60aff1f' User entered 'None (0)'	System	17 Sep 2020 02:23:31
	System	17 Sep 2020 02:23:31

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-16T21:23:23', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'bec9a10c-51a3-420a-ac93-87bcc60aff1f' User entered 'None (0)'	System	17 Sep 2020 02:23:31
	System	17 Sep 2020 02:23:31



US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-16T21:23:25', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'bec9a10c-51a3-420a-ac93-87bcc60aff1f' User entered 'No (N)'	System	17 Sep 2020 02:23:31
	System	17 Sep 2020 02:23:31

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-16T21:23:28', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'bec9a10c-51a3-420a-ac93-87bcc60aff1f' User entered '16 Sep 2020 21:23'	System	17 Sep 2020 02:23:31
	System	17 Sep 2020 02:23:31

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	15 Sep 2020 16:09:26
User entered 'Day 3'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-18T05:59:45', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'aa699bdf-80e9-4240-b938-f7b0093d6b4b' User entered 'None (0)'	System	18 Sep 2020 11:00:21
	System	18 Sep 2020 11:00:21

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-18T05:59:48', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'aa699bdf-80e9-4240-b938-f7b0093d6b4b' User entered 'None (0)'	System	18 Sep 2020 11:00:21
	System	18 Sep 2020 11:00:21

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-18T05:59:50', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'aa699bdf-80e9-4240-b938-f7b0093d6b4b' User entered 'None (0)'	System	18 Sep 2020 11:00:21
	System	18 Sep 2020 11:00:21



US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-18T05:59:53', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'aa699bdf-80e9-4240-b938-f7b0093d6b4b' User entered 'None (0)'	System	18 Sep 2020 11:00:21
	System	18 Sep 2020 11:00:21

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-18T05:59:56', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'aa699bdf-80e9-4240-b938-f7b0093d6b4b' User entered 'None (0)'	System	18 Sep 2020 11:00:21
	System	18 Sep 2020 11:00:21

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-18T05:59:58', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'aa699bdf-80e9-4240-b938-f7b0093d6b4b' User entered 'None (0)'	System	18 Sep 2020 11:00:21
	System	18 Sep 2020 11:00:21

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-18T06:00:01', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'aa699bdf-80e9-4240-b938-f7b0093d6b4b' User entered 'No (N)'	System	18 Sep 2020 11:00:21
	System	18 Sep 2020 11:00:21

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:34:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-18T06:00:04', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'aa699bdf-80e9-4240-b938-f7b0093d6b4b' User entered '18 Sep 2020 06:00'	System	18 Sep 2020 11:00:21
	System	18 Sep 2020 11:00:21

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 16:09:26

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:34:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	15 Sep 2020 16:09:26
User entered 'Day 4'	System	15 Sep 2020 16:09:26



US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-19T06:55:15', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'a7024072-3e16-4e7b-8599-e47d8268d545' User entered 'None (0)'	System	19 Sep 2020 11:55:38
	System	19 Sep 2020 11:55:38

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-19T06:55:17', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'a7024072-3e16-4e7b-8599-e47d8268d545' User entered 'None (0)'	System	19 Sep 2020 11:55:38
	System	19 Sep 2020 11:55:38

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-19T06:55:19', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'a7024072-3e16-4e7b-8599-e47d8268d545' User entered 'None (0)'	System	19 Sep 2020 11:55:38
	System	19 Sep 2020 11:55:38

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-19T06:55:21', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'a7024072-3e16-4e7b-8599-e47d8268d545' User entered 'None (0)'	System	19 Sep 2020 11:55:38
	System	19 Sep 2020 11:55:38

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-19T06:55:23', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'a7024072-3e16-4e7b-8599-e47d8268d545' User entered 'None (0)'	System	19 Sep 2020 11:55:38
	System	19 Sep 2020 11:55:38

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-19T06:55:25', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'a7024072-3e16-4e7b-8599-e47d8268d545' User entered 'None (0)'	System	19 Sep 2020 11:55:38
	System	19 Sep 2020 11:55:38

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-19T06:55:28', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'a7024072-3e16-4e7b-8599-e47d8268d545'	System	19 Sep 2020 11:55:38
User entered 'No (N)'	System	19 Sep 2020 11:55:38

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-19T06:55:34', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'a7024072-3e16-4e7b-8599-e47d8268d545' User entered '19 Sep 2020 06:55'	System	19 Sep 2020 11:55:38
	System	19 Sep 2020 11:55:38



US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	15 Sep 2020 16:09:26
User entered 'Day 5'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-20T07:06:04', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '868d341e-59d3-4582-8163-a3d5b5dffb1' User entered 'None (0)'	System	20 Sep 2020 12:06:21
	System	20 Sep 2020 12:06:21

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-20T07:06:05', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '868d341e-59d3-4582-8163-a3d5b5dffb1' User entered 'None (0)'	System	20 Sep 2020 12:06:21
	System	20 Sep 2020 12:06:21

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-20T07:06:07', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '868d341e-59d3-4582-8163-a3d5b5dffb1' User entered 'None (0)'	System	20 Sep 2020 12:06:21
	System	20 Sep 2020 12:06:21

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-20T07:06:09', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '868d341e-59d3-4582-8163-a3d5b5dffb1' User entered 'None (0)'	System	20 Sep 2020 12:06:21
	System	20 Sep 2020 12:06:21

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-20T07:06:11', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '868d341e-59d3-4582-8163-a3d5b5dffb1' User entered 'None (0)'	System	20 Sep 2020 12:06:21
	System	20 Sep 2020 12:06:21



US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-20T07:06:13', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '868d341e-59d3-4582-8163-a3d5b5dffb1' User entered 'None (0)'	System	20 Sep 2020 12:06:21
	System	20 Sep 2020 12:06:21

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-20T07:06:16', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '868d341e-59d3-4582-8163-a3d5b5dffb1' User entered 'No (N)'	System	20 Sep 2020 12:06:21
	System	20 Sep 2020 12:06:21

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:34:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-20T07:06:19', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '868d341e-59d3-4582-8163-a3d5b5dffb1' User entered '20 Sep 2020 07:06'	System	20 Sep 2020 12:06:21
	System	20 Sep 2020 12:06:21

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	15 Sep 2020 16:09:26
User entered 'Day 6'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-21T08:45:52', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'b683f96c-0874-4a4c-97d9-3f52575157b8' User entered 'None (0)'	System	21 Sep 2020 13:46:21
	System	21 Sep 2020 13:46:21

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-21T08:45:54', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'b683f96c-0874-4a4c-97d9-3f52575157b8' User entered 'None (0)'	System	21 Sep 2020 13:46:21
	System	21 Sep 2020 13:46:21



US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-21T08:45:57', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'b683f96c-0874-4a4c-97d9-3f52575157b8' User entered 'None (0)'	System	21 Sep 2020 13:46:21
	System	21 Sep 2020 13:46:21

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-21T08:46:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'b683f96c-0874-4a4c-97d9-3f52575157b8' User entered 'None (0)'	System	21 Sep 2020 13:46:21
	System	21 Sep 2020 13:46:21

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-21T08:46:07', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'b683f96c-0874-4a4c-97d9-3f52575157b8' User entered 'None (0)'	System	21 Sep 2020 13:46:21
	System	21 Sep 2020 13:46:21

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-21T08:46:11', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'b683f96c-0874-4a4c-97d9-3f52575157b8' User entered 'None (0)'	System	21 Sep 2020 13:46:21
	System	21 Sep 2020 13:46:21

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-21T08:46:14', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'b683f96c-0874-4a4c-97d9-3f52575157b8' User entered 'No (N)'	System	21 Sep 2020 13:46:21
	System	21 Sep 2020 13:46:21

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-21T08:46:16', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'b683f96c-0874-4a4c-97d9-3f52575157b8' User entered '21 Sep 2020 08:46'	System	21 Sep 2020 13:46:21
	System	21 Sep 2020 13:46:21

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 16:09:26



US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	15 Sep 2020 16:09:26
User entered 'Day 7'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-22T08:44:47', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'da860342-c03e-4740-a0b3-3c5024640fd9' User entered 'None (0)'	System	22 Sep 2020 13:45:08
	System	22 Sep 2020 13:45:08

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-22T08:44:49', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'da860342-c03e-4740-a0b3-3c5024640fd9' User entered 'None (0)'	System	22 Sep 2020 13:45:08
	System	22 Sep 2020 13:45:08

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-22T08:44:52', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'da860342-c03e-4740-a0b3-3c5024640fd9' User entered 'None (0)'	System	22 Sep 2020 13:45:08
	System	22 Sep 2020 13:45:08

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-22T08:44:55', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'da860342-c03e-4740-a0b3-3c5024640fd9' User entered 'None (0)'	System	22 Sep 2020 13:45:08
	System	22 Sep 2020 13:45:08

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-22T08:44:57', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'da860342-c03e-4740-a0b3-3c5024640fd9' User entered 'None (0)'	System	22 Sep 2020 13:45:08
	System	22 Sep 2020 13:45:08

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-22T08:44:59', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'da860342-c03e-4740-a0b3-3c5024640fd9' User entered 'None (0)'	System	22 Sep 2020 13:45:08
	System	22 Sep 2020 13:45:08

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-22T08:45:02', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'da860342-c03e-4740-a0b3-3c5024640fd9' User entered 'No (N)'	System	22 Sep 2020 13:45:08
	System	22 Sep 2020 13:45:08



US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-09-22T08:45:04', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'da860342-c03e-4740-a0b3-3c5024640fd9' User entered '22 Sep 2020 08:45'	System	22 Sep 2020 13:45:08
	System	22 Sep 2020 13:45:08

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 16:09:26

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 16:09:26

US3422281

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 22:16:17

US3422281

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 22:16:17

US3422281

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 22:16:17

US3422281

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 22:16:17

US3422281

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 22:16:23



US3422281

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'I'	System	22 Sep 2020 22:16:23

US3422281

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 18:05:29

US3422281

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 18:05:29

US3422281

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 18:05:29

US3422281

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 18:05:29

US3422281

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 18:05:38

US3422281

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'I'	System	30 Sep 2020 18:05:38

US3422281

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	Wendy Winn (b) (4)	06 Oct 2020 19:07:03



US3422281

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '6 Oct 2020'	Wendy Winn (b) (4)	06 Oct 2020 19:07:03

US3422281

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Contact Made (CONTACT MADE)'	Wendy Winn (b) (4)	06 Oct 2020 19:07:03

US3422281

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	Wendy Winn (b) (4)	06 Oct 2020 19:07:03

US3422281

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	Wendy Winn (b) (4)	06 Oct 2020 19:07:07

**US3422281**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'I'	System	06 Oct 2020 19:07:07

US3422281

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:28:49

US3422281

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:28:49

US3422281

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:28:49



**US3422281**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'VISIT2'	System	14 Oct 2020 16:28:49

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '09:58'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered '14 Oct 2020 09:58'	System	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '98.1' F	(b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:31:32



US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '075'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'bpm'	System	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '014'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'breaths/min'	System	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '139'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'mmHg'	System	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '065'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:31:32



US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'mmHg'	System	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Oct 2020 16:31:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 16:31:55
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 16:31:55
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 16:31:32
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '11:08'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered '14 Oct 2020 11:08'	System	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:31:32



US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '057'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'bpm'	System	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '012'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'breaths/min'	System	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '131'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'mmHg'	System	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User closed query 'Per CDM re-query: This value is out of range as per protocol. Please confirm in query response if this value should be considered as NCS. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:31:41
Query 'Per CDM re-query: This value is out of range as per protocol. Please confirm in query response if this value should be considered as NCS. ' answered with 'NCS' (Site from DM).	April Hanlotxomphou (b) (4)	04 Dec 2020 18:32:30
User closed query 'Per CDM: Please confirm if the out of range value should be considered as clinically significant or not as per PI.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:06:31
User opened query 'Per CDM re-query: This value is out of range as per protocol. Please confirm in query response if this value should be considered as NCS. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:06:27
Query 'Per CDM: Please confirm if the out of range value should be considered as clinically significant or not as per PI.' answered with 'review to memo to file in chart' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 21:16:27
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	08 Nov 2020 04:47:28
User opened query 'Per CDM: Please confirm if the out of range value should be considered as clinically significant or not as per PI.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 04:47:26
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'memo in chart' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 14:00:49
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		14 Oct 2020 16:31:32
User entered '058'	(b) (4), (b) (6)	14 Oct 2020 16:31:32



US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'mmHg'	System	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:32:59

US3422281

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:32:59

US3422281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:53:43
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.'	Wendy Winn (b) (4)	14 Oct 2020 15:43:20
answered with 'correct' (Site from System).	(b) (4)	
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	14 Oct 2020 15:42:57
User entered 'Yes (Y)'	Wendy Winn (b) (4) (b) (4)	14 Oct 2020 15:42:57

US3422281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	(b) (4) Wendy Winn (b) (4) (b) (4)	14 Oct 2020 15:42:57

US3422281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	Wendy Winn (b) (4)	14 Oct 2020 15:42:57

US3422281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'MRNA-1273 OR PLACEBO'	System	14 Oct 2020 15:42:57

US3422281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '14 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Wendy Winn (b) (4)	14 Oct 2020 16:10:06
User entered empty.	(b) (4)	
	Wendy Winn (b) (4)	14 Oct 2020 15:42:57
	(b) (4)	



US3422281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '10:38'	Wendy Winn (b) (4)	14 Oct 2020 15:42:57

US3422281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered '14 Oct 2020 10:38'	System	14 Oct 2020 16:10:06
User entered empty.	System	14 Oct 2020 15:42:57

US3422281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Wendy Winn (b) (4)	14 Oct 2020 15:42:57
	(b) (4)	

US3422281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'ONCE'	System	14 Oct 2020 15:42:57

US3422281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'INTRAMUSCULAR'	System	14 Oct 2020 15:42:57

US3422281

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:33:40

US3422281

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:33:40

US3422281

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '10:05'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:33:40



US3422281

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered '14 Oct 2020 10:05'	System	14 Oct 2020 16:33:40

US3422281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:34:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:34:23

US3422281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	14 Oct 2020 16:34:23

US3422281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:34:23

US3422281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '10:03'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:34:23

**US3422281**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered '14 Oct 2020 10:03'	System	14 Oct 2020 16:34:23

US3422281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	14 Oct 2020 16:34:23

US3422281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:34:23



US3422281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:34:23

**US3422281**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:34:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered empty.	System	14 Oct 2020 16:34:23

US3422281

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:34:35

**US3422281**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered '1'	System	14 Oct 2020 16:34:35

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	14 Oct 2020 16:10:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T11:10:52', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'd01cb829-f51c-4264-a49c-4c763b899a40' User entered 'Yes (Y)'	System	14 Oct 2020 16:11:11
	System	14 Oct 2020 16:11:11

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T11:10:58', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'd01cb829-f51c-4264-a49c-4c763b899a40' User entered '98.7'	System	14 Oct 2020 16:11:11
	System	14 Oct 2020 16:11:11

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T11:11:01', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'd01cb829-f51c-4264-a49c-4c763b899a40' User entered 'No (N)'	System	14 Oct 2020 16:11:11
	System	14 Oct 2020 16:11:11



US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T11:11:08', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'd01cb829-f51c-4264-a49c-4c763b899a40' User entered '14 Oct 2020 11:11'	System	14 Oct 2020 16:11:11
	System	14 Oct 2020 16:11:11

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '14 Oct 2020 10:58'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '14 Oct 2020 13:28'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	14 Oct 2020 16:10:06
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T14:30:16', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'a1410185-2b8f-4c42-9d81-f823ba8e217f' User entered 'Yes (Y)'	System	14 Oct 2020 19:31:30
	System	14 Oct 2020 19:31:30

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T14:31:21', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'a1410185-2b8f-4c42-9d81-f823ba8e217f' User entered '98.2'	System	14 Oct 2020 19:31:30
	System	14 Oct 2020 19:31:30

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T14:31:24', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'a1410185-2b8f-4c42-9d81-f823ba8e217f' User entered 'No (N)'	System	14 Oct 2020 19:31:30
	System	14 Oct 2020 19:31:30

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T14:31:28', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'a1410185-2b8f-4c42-9d81-f823ba8e217f' User entered '14 Oct 2020 14:31'	System	14 Oct 2020 19:31:30
	System	14 Oct 2020 19:31:30



US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '14 Oct 2020 14:23'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	14 Oct 2020 16:10:06
User entered 'Day 2'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-16T05:59:13', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'ab9de682-2795-43b4-989a-bb7ed13f4584' User entered 'Yes (Y)'	System	16 Oct 2020 10:59:43
	System	16 Oct 2020 10:59:43

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-16T05:59:23', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'ab9de682-2795-43b4-989a-bb7ed13f4584' User entered '98.1'	System	16 Oct 2020 10:59:43
	System	16 Oct 2020 10:59:43

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-16T05:59:36', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'ab9de682-2795-43b4-989a-bb7ed13f4584' User entered 'No (N)'	System	16 Oct 2020 10:59:43
	System	16 Oct 2020 10:59:43

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-16T05:59:40', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'ab9de682-2795-43b4-989a-bb7ed13f4584' User entered '16 Oct 2020 05:59'	System	16 Oct 2020 10:59:43
	System	16 Oct 2020 10:59:43

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 16:10:06



US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	14 Oct 2020 16:10:06
User entered 'Day 3'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-17T08:59:24', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '47055fca-8ee8-4acd-b7fe-482455814b71' User entered 'Yes (Y)'	System	17 Oct 2020 13:59:41
	System	17 Oct 2020 13:59:41

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-17T08:59:33', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '47055fca-8ee8-4acd-b7fe-482455814b71' User entered '97.8'	System	17 Oct 2020 13:59:41
	System	17 Oct 2020 13:59:41

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-17T08:59:37', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '47055fca-8ee8-4acd-b7fe-482455814b71' User entered 'No (N)'	System	17 Oct 2020 13:59:41
	System	17 Oct 2020 13:59:41

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-17T08:59:39', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '47055fca-8ee8-4acd-b7fe-482455814b71' User entered '17 Oct 2020 08:59'	System	17 Oct 2020 13:59:41
	System	17 Oct 2020 13:59:41

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 16:10:06



US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	14 Oct 2020 16:10:06
User entered 'Day 4'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-18T07:45:51', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '77d2acef-43d8-4497-afa0-a2eb0fb2e357' User entered 'Yes (Y)'	System	18 Oct 2020 12:46:13
	System	18 Oct 2020 12:46:13

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-18T07:45:58', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '77d2acef-43d8-4497-afa0-a2eb0fb2e357' User entered '98.4'	System	18 Oct 2020 12:46:13
	System	18 Oct 2020 12:46:13

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-18T07:46:06', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '77d2acef-43d8-4497-afa0-a2eb0fb2e357'	System	18 Oct 2020 12:46:13
User entered 'No (N)'	System	18 Oct 2020 12:46:13

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-18T07:46:11', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '77d2acef-43d8-4497-afa0-a2eb0fb2e357' User entered '18 Oct 2020 07:46'	System	18 Oct 2020 12:46:13
	System	18 Oct 2020 12:46:13

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	14 Oct 2020 16:10:06
User entered 'Day 5'	System	14 Oct 2020 16:10:06



US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-19T09:58:41', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '6c96c17d-4146-495f-975d-2ed3fd97e64f' User entered 'Yes (Y)'	System	19 Oct 2020 15:08:23
	System	19 Oct 2020 15:08:23

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-19T09:58:48', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '6c96c17d-4146-495f-975d-2ed3fd97e64f' User entered '98.2'	System	19 Oct 2020 15:08:23
	System	19 Oct 2020 15:08:23

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-19T09:58:51', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '6c96c17d-4146-495f-975d-2ed3fd97e64f' User entered 'No (N)'	System	19 Oct 2020 15:08:23
	System	19 Oct 2020 15:08:23

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-19T09:58:54', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '6c96c17d-4146-495f-975d-2ed3fd97e64f' User entered '19 Oct 2020 09:58'	System	19 Oct 2020 15:08:23
	System	19 Oct 2020 15:08:23

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	14 Oct 2020 16:10:06
User entered 'Day 6'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-20T06:34:34', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '4f7ee0da-3c83-4ac2-88fb-b9f14ac66aa3' User entered 'Yes (Y)'	System	20 Oct 2020 11:34:51
	System	20 Oct 2020 11:34:51



US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-20T06:34:41', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '4f7ee0da-3c83-4ac2-88fb-b9f14ac66aa3' User entered '97.8'	System	20 Oct 2020 11:34:51
	System	20 Oct 2020 11:34:51

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-20T06:34:43', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '4f7ee0da-3c83-4ac2-88fb-b9f14ac66aa3' User entered 'No (N)'	System	20 Oct 2020 11:34:51
	System	20 Oct 2020 11:34:51

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:34:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-20T06:34:48', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '4f7ee0da-3c83-4ac2-88fb-b9f14ac66aa3' User entered '20 Oct 2020 06:34'	System	20 Oct 2020 11:34:51
	System	20 Oct 2020 11:34:51

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	14 Oct 2020 16:10:06
User entered 'Day 7'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-21T06:24:42', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'e4d4421e-36df-43ca-bfb1-29dbf6a9118f' User entered 'Yes (Y)'	System	21 Oct 2020 11:25:01
	System	21 Oct 2020 11:25:01

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-21T06:24:51', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'e4d4421e-36df-43ca-bfb1-29dbf6a9118f' User entered '97.8'	System	21 Oct 2020 11:25:01
	System	21 Oct 2020 11:25:01



US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-21T06:24:54', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'e4d4421e-36df-43ca-bfb1-29dbf6a9118f' User entered 'No (N)'	System	21 Oct 2020 11:25:01
	System	21 Oct 2020 11:25:01

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-21T06:24:58', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'e4d4421e-36df-43ca-bfb1-29dbf6a9118f' User entered '21 Oct 2020 06:24'	System	21 Oct 2020 11:25:01
	System	21 Oct 2020 11:25:01

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	14 Oct 2020 16:10:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T11:11:23', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'f91531aa-2310-44b6-8189-bb9b487e66f7'	System	14 Oct 2020 16:11:50
User entered 'Does not interfere with activity (2)'	System	14 Oct 2020 16:11:50

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T11:11:28', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'f91531aa-2310-44b6-8189-bb9b487e66f7' User entered 'No (N)'	System	14 Oct 2020 16:11:50
	System	14 Oct 2020 16:11:50

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T11:11:34', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'f91531aa-2310-44b6-8189-bb9b487e66f7' User entered 'No (N)'	System	14 Oct 2020 16:11:50
	System	14 Oct 2020 16:11:50



US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T11:11:40', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'f91531aa-2310-44b6-8189-bb9b487e66f7' User entered 'None (1)'	System	14 Oct 2020 16:11:50
	System	14 Oct 2020 16:11:50

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T11:11:43', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'f91531aa-2310-44b6-8189-bb9b487e66f7' User entered '14 Oct 2020 11:11'	System	14 Oct 2020 16:11:50
	System	14 Oct 2020 16:11:50

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '14 Oct 2020 10:58'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '14 Oct 2020 13:28'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	14 Oct 2020 16:10:06
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T14:31:32', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '4dcb05f3-6f7e-4df5-a0b8-675c6e01ca4f' User entered 'None (1)'	System	14 Oct 2020 19:31:45
	System	14 Oct 2020 19:31:45

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T14:31:34', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '4dcb05f3-6f7e-4df5-a0b8-675c6e01ca4f' User entered 'No (N)'	System	14 Oct 2020 19:31:45
	System	14 Oct 2020 19:31:45

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T14:31:37', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '4dcb05f3-6f7e-4df5-a0b8-675c6e01ca4f' User entered 'No (N)'	System	14 Oct 2020 19:31:45
	System	14 Oct 2020 19:31:45



US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T14:31:40', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '4dc05f3-6f7e-4df5-a0b8-675c6e01ca4f' User entered 'None (1)'	System	14 Oct 2020 19:31:45
	System	14 Oct 2020 19:31:45

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T14:31:43', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '4dc05f3-6f7e-4df5-a0b8-675c6e01ca4f' User entered '14 Oct 2020 14:31'	System	14 Oct 2020 19:31:45
	System	14 Oct 2020 19:31:45

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '14 Oct 2020 14:23'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	14 Oct 2020 16:10:06
User entered 'Day 2'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-16T05:59:45', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'ef3beb0d-2c4f-4917-a446-780719592835'	System	16 Oct 2020 10:59:59
User entered 'None (1)'	System	16 Oct 2020 10:59:59

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-16T05:59:48', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'ef3beb0d-2c4f-4917-a446-780719592835'	System	16 Oct 2020 10:59:59
User entered 'No (N)'	System	16 Oct 2020 10:59:59

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-16T05:59:50', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'ef3beb0d-2c4f-4917-a446-780719592835' User entered 'No (N)'	System	16 Oct 2020 10:59:59
	System	16 Oct 2020 10:59:59



US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-16T05:59:54', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'ef3beb0d-2c4f-4917-a446-780719592835'	System	16 Oct 2020 10:59:59
User entered 'None (1)'	System	16 Oct 2020 10:59:59

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-16T05:59:56', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'ef3beb0d-2c4f-4917-a446-780719592835' User entered '16 Oct 2020 05:59'	System	16 Oct 2020 10:59:59
	System	16 Oct 2020 10:59:59

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	14 Oct 2020 16:10:06
User entered 'Day 3'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-17T08:59:44', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'b98ba963-9052-4cb0-8b31-497b9d6e8652'	System	17 Oct 2020 14:00:06
User entered 'None (1)'	System	17 Oct 2020 14:00:06

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-17T08:59:48', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'b98ba963-9052-4cb0-8b31-497b9d6e8652'	System	17 Oct 2020 14:00:06
User entered 'No (N)'	System	17 Oct 2020 14:00:06

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-17T08:59:52', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'b98ba963-9052-4cb0-8b31-497b9d6e8652'	System	17 Oct 2020 14:00:06
User entered 'No (N)'	System	17 Oct 2020 14:00:06



US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-17T09:00:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'b98ba963-9052-4cb0-8b31-497b9d6e8652'	System	17 Oct 2020 14:00:06
User entered 'None (1)'	System	17 Oct 2020 14:00:06

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-17T09:00:03', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'b98ba963-9052-4cb0-8b31-497b9d6e8652'	System	17 Oct 2020 14:00:06
User entered '17 Oct 2020 09:00'	System	17 Oct 2020 14:00:06

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	14 Oct 2020 16:10:06
User entered 'Day 4'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-18T07:46:14', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '5e47fb97-9a0d-4b0a-80fe-945e8d0da45f' User entered 'None (1)'	System	18 Oct 2020 12:46:39
	System	18 Oct 2020 12:46:39

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-18T07:46:20', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '5e47fb97-9a0d-4b0a-80fe-945e8d0da45f' User entered 'No (N)'	System	18 Oct 2020 12:46:39
	System	18 Oct 2020 12:46:39

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-18T07:46:22', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '5e47fb97-9a0d-4b0a-80fe-945e8d0da45f' User entered 'No (N)'	System	18 Oct 2020 12:46:39
	System	18 Oct 2020 12:46:39



US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-18T07:46:33', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '5e47fb97-9a0d-4b0a-80fe-945e8d0da45f' User entered 'None (1)'	System	18 Oct 2020 12:46:39
	System	18 Oct 2020 12:46:39

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-18T07:46:37', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '5e47fb97-9a0d-4b0a-80fe-945e8d0da45f' User entered '18 Oct 2020 07:46'	System	18 Oct 2020 12:46:39
	System	18 Oct 2020 12:46:39

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	14 Oct 2020 16:10:06
User entered 'Day 5'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-19T09:58:57', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'eb838871-5a44-47c2-8731-7ba85e6c1624'	System	19 Oct 2020 15:08:27
User entered 'None (1)'	System	19 Oct 2020 15:08:27

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-19T09:59:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'eb838871-5a44-47c2-8731-7ba85e6c1624' User entered 'No (N)'	System	19 Oct 2020 15:08:27
	System	19 Oct 2020 15:08:27

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-19T09:59:01', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'eb838871-5a44-47c2-8731-7ba85e6c1624' User entered 'No (N)'	System	19 Oct 2020 15:08:27
	System	19 Oct 2020 15:08:27



US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-19T09:59:03', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'eb838871-5a44-47c2-8731-7ba85e6c1624'	System	19 Oct 2020 15:08:27
User entered 'None (1)'	System	19 Oct 2020 15:08:27

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:34:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-19T09:59:06', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'eb838871-5a44-47c2-8731-7ba85e6c1624' User entered '19 Oct 2020 09:59'	System	19 Oct 2020 15:08:27
	System	19 Oct 2020 15:08:27

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	14 Oct 2020 16:10:06
User entered 'Day 6'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-20T06:34:52', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '7df0de4d-ed90-4aa5-bbef-0f5095918556'	System	20 Oct 2020 11:35:08
User entered 'None (1)'	System	20 Oct 2020 11:35:08

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-20T06:34:55', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '7df0de4d-ed90-4aa5-bbef-0f5095918556'	System	20 Oct 2020 11:35:08
User entered 'No (N)'	System	20 Oct 2020 11:35:08

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-20T06:34:59', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '7df0de4d-ed90-4aa5-bbef-0f5095918556'	System	20 Oct 2020 11:35:08
User entered 'No (N)'	System	20 Oct 2020 11:35:08



US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-20T06:35:05', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '7df0de4d-ed90-4aa5-bbef-0f5095918556'	System	20 Oct 2020 11:35:08
User entered 'None (1)'	System	20 Oct 2020 11:35:08

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-20T06:35:07', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '7df0de4d-ed90-4aa5-bbef-0f5095918556'	System	20 Oct 2020 11:35:08
User entered '20 Oct 2020 06:35'	System	20 Oct 2020 11:35:08

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 16:10:06

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:34:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	14 Oct 2020 16:10:06
User entered 'Day 7'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-21T06:25:02', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'c97d68fd-5916-4d7a-a39b-e77228ecf8c9'	System	21 Oct 2020 11:25:19
User entered 'None (1)'	System	21 Oct 2020 11:25:19

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-21T06:25:08', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'c97d68fd-5916-4d7a-a39b-e77228ecf8c9' User entered 'No (N)'	System	21 Oct 2020 11:25:19
	System	21 Oct 2020 11:25:19

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-21T06:25:11', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'c97d68fd-5916-4d7a-a39b-e77228ecf8c9' User entered 'No (N)'	System	21 Oct 2020 11:25:19
	System	21 Oct 2020 11:25:19



US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-21T06:25:14', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'c97d68fd-5916-4d7a-a39b-e77228ecf8c9' User entered 'None (1)'	System	21 Oct 2020 11:25:19
	System	21 Oct 2020 11:25:19

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-21T06:25:17', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'c97d68fd-5916-4d7a-a39b-e77228ecf8c9' User entered '21 Oct 2020 06:25'	System	21 Oct 2020 11:25:19
	System	21 Oct 2020 11:25:19

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	14 Oct 2020 16:10:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T11:11:47', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'fd17f5e7-73ec-4ae2-ab22-95b41125c47c' User entered 'None (0)'	System	14 Oct 2020 16:12:14
	System	14 Oct 2020 16:12:14

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T11:11:50', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'fd17f5e7-73ec-4ae2-ab22-95b41125c47c' User entered 'None (0)'	System	14 Oct 2020 16:12:14
	System	14 Oct 2020 16:12:14

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T11:11:53', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'fd17f5e7-73ec-4ae2-ab22-95b41125c47c' User entered 'None (0)'	System	14 Oct 2020 16:12:14
	System	14 Oct 2020 16:12:14



US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T11:11:58', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'fd17f5e7-73ec-4ae2-ab22-95b41125c47c' User entered 'None (0)'	System	14 Oct 2020 16:12:14
	System	14 Oct 2020 16:12:14

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T11:12:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'fd17f5e7-73ec-4ae2-ab22-95b41125c47c' User entered 'None (0)'	System	14 Oct 2020 16:12:14
	System	14 Oct 2020 16:12:14

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T11:12:03', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'fd17f5e7-73ec-4ae2-ab22-95b41125c47c' User entered 'None (0)'	System	14 Oct 2020 16:12:14
	System	14 Oct 2020 16:12:14

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T11:12:05', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'fd17f5e7-73ec-4ae2-ab22-95b41125c47c' User entered 'No (N)'	System	14 Oct 2020 16:12:14
	System	14 Oct 2020 16:12:14

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T11:12:09', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'fd17f5e7-73ec-4ae2-ab22-95b41125c47c' User entered '14 Oct 2020 11:12'	System	14 Oct 2020 16:12:14
	System	14 Oct 2020 16:12:14

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '14 Oct 2020 10:58'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '14 Oct 2020 13:28'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	14 Oct 2020 16:10:06
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 16:10:06



US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T14:31:47', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0d4319ba-4523-4c36-b348-7da2395da2a4' User entered 'None (0)'	System	14 Oct 2020 19:32:08
	System	14 Oct 2020 19:32:08

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T14:31:49', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0d4319ba-4523-4c36-b348-7da2395da2a4' User entered 'None (0)'	System	14 Oct 2020 19:32:08
	System	14 Oct 2020 19:32:08

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T14:31:51', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0d4319ba-4523-4c36-b348-7da2395da2a4' User entered 'None (0)'	System	14 Oct 2020 19:32:08
	System	14 Oct 2020 19:32:08

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T14:31:54', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0d4319ba-4523-4c36-b348-7da2395da2a4' User entered 'None (0)'	System	14 Oct 2020 19:32:08
	System	14 Oct 2020 19:32:08

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T14:31:56', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0d4319ba-4523-4c36-b348-7da2395da2a4' User entered 'None (0)'	System	14 Oct 2020 19:32:08
	System	14 Oct 2020 19:32:08

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T14:31:58', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0d4319ba-4523-4c36-b348-7da2395da2a4' User entered 'None (0)'	System	14 Oct 2020 19:32:08
	System	14 Oct 2020 19:32:08

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T14:32:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0d4319ba-4523-4c36-b348-7da2395da2a4'	System	14 Oct 2020 19:32:08
User entered 'No (N)'	System	14 Oct 2020 19:32:08

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:34:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-14T14:32:02', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0d4319ba-4523-4c36-b348-7da2395da2a4' User entered '14 Oct 2020 14:32'	System	14 Oct 2020 19:32:08
	System	14 Oct 2020 19:32:08



US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '14 Oct 2020 14:23'	System	14 Oct 2020 16:10:06

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:34:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	14 Oct 2020 16:10:06
User entered 'Day 2'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-16T06:00:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'de62b7da-ff02-46a6-92f0-aa87baeb8516' User entered 'None (0)'	System	16 Oct 2020 11:00:19
	System	16 Oct 2020 11:00:19

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-16T06:00:04', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'de62b7da-ff02-46a6-92f0-aa87baeb8516' User entered 'None (0)'	System	16 Oct 2020 11:00:19
	System	16 Oct 2020 11:00:19

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-16T06:00:07', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'de62b7da-ff02-46a6-92f0-aa87baeb8516' User entered 'None (0)'	System	16 Oct 2020 11:00:19
	System	16 Oct 2020 11:00:19

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-16T06:00:08', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'de62b7da-ff02-46a6-92f0-aa87baeb8516' User entered 'None (0)'	System	16 Oct 2020 11:00:19
	System	16 Oct 2020 11:00:19

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-16T06:00:10', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'de62b7da-ff02-46a6-92f0-aa87baeb8516' User entered 'None (0)'	System	16 Oct 2020 11:00:19
	System	16 Oct 2020 11:00:19



US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-16T06:00:12', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'de62b7da-ff02-46a6-92f0-aa87baeb8516' User entered 'None (0)'	System	16 Oct 2020 11:00:19
	System	16 Oct 2020 11:00:19

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-16T06:00:15', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'de62b7da-ff02-46a6-92f0-aa87baeb8516' User entered 'No (N)'	System	16 Oct 2020 11:00:19
	System	16 Oct 2020 11:00:19

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-16T06:00:18', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'de62b7da-ff02-46a6-92f0-aa87baeb8516' User entered '16 Oct 2020 06:00'	System	16 Oct 2020 11:00:19
	System	16 Oct 2020 11:00:19

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	14 Oct 2020 16:10:06
User entered 'Day 3'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-17T09:00:08', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '61f249ac-f302-48a2-9cd9-034f6556488f' User entered 'None (0)'	System	17 Oct 2020 14:00:26
	System	17 Oct 2020 14:00:26

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-17T09:00:09', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '61f249ac-f302-48a2-9cd9-034f6556488f' User entered 'None (0)'	System	17 Oct 2020 14:00:26
	System	17 Oct 2020 14:00:26



US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-17T09:00:12', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '61f249ac-f302-48a2-9cd9-034f6556488f' User entered 'None (0)'	System	17 Oct 2020 14:00:26
	System	17 Oct 2020 14:00:26

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-17T09:00:14', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '61f249ac-f302-48a2-9cd9-034f6556488f' User entered 'None (0)'	System	17 Oct 2020 14:00:26
	System	17 Oct 2020 14:00:26

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-17T09:00:16', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '61f249ac-f302-48a2-9cd9-034f6556488f' User entered 'None (0)'	System	17 Oct 2020 14:00:26
	System	17 Oct 2020 14:00:26

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-17T09:00:18', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '61f249ac-f302-48a2-9cd9-034f6556488f' User entered 'None (0)'	System	17 Oct 2020 14:00:26
	System	17 Oct 2020 14:00:26

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-17T09:00:20', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '61f249ac-f302-48a2-9cd9-034f6556488f' User entered 'No (N)'	System	17 Oct 2020 14:00:26
	System	17 Oct 2020 14:00:26

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-17T09:00:23', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '61f249ac-f302-48a2-9cd9-034f6556488f' User entered '17 Oct 2020 09:00'	System	17 Oct 2020 14:00:26
	System	17 Oct 2020 14:00:26

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 16:10:06

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:34:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 16:10:06



US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	14 Oct 2020 16:10:06
User entered 'Day 4'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-18T07:46:41', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '9b69d9d8-46c1-483f-9d7b-cbca48f7d812' User entered 'None (0)'	System	18 Oct 2020 12:46:58
	System	18 Oct 2020 12:46:58

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-18T07:46:43', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '9b69d9d8-46c1-483f-9d7b-cbca48f7d812' User entered 'None (0)'	System	18 Oct 2020 12:46:58
	System	18 Oct 2020 12:46:58

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-18T07:46:45', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '9b69d9d8-46c1-483f-9d7b-cbca48f7d812' User entered 'None (0)'	System	18 Oct 2020 12:46:58
	System	18 Oct 2020 12:46:58

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-18T07:46:46', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '9b69d9d8-46c1-483f-9d7b-cbca48f7d812' User entered 'None (0)'	System	18 Oct 2020 12:46:58
	System	18 Oct 2020 12:46:58

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-18T07:46:48', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '9b69d9d8-46c1-483f-9d7b-cbca48f7d812' User entered 'None (0)'	System	18 Oct 2020 12:46:58
	System	18 Oct 2020 12:46:58

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-18T07:46:50', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '9b69d9d8-46c1-483f-9d7b-cbca48f7d812' User entered 'None (0)'	System	18 Oct 2020 12:46:58
	System	18 Oct 2020 12:46:58

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-18T07:46:52', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '9b69d9d8-46c1-483f-9d7b-cbca48f7d812' User entered 'No (N)'	System	18 Oct 2020 12:46:58
	System	18 Oct 2020 12:46:58



**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:34:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-18T07:46:55', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '9b69d9d8-46c1-483f-9d7b-cbca48f7d812' User entered '18 Oct 2020 07:46'	System	18 Oct 2020 12:46:58
	System	18 Oct 2020 12:46:58

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	14 Oct 2020 16:10:06
User entered 'Day 5'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-19T09:59:09', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '476b2e2a-6947-44dd-ada7-387368deb944' User entered 'None (0)'	System	19 Oct 2020 15:08:29
	System	19 Oct 2020 15:08:29

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-19T09:59:11', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '476b2e2a-6947-44dd-ada7-387368deb944' User entered 'None (0)'	System	19 Oct 2020 15:08:29
	System	19 Oct 2020 15:08:29

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-19T09:59:13', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '476b2e2a-6947-44dd-ada7-387368deb944' User entered 'None (0)'	System	19 Oct 2020 15:08:29
	System	19 Oct 2020 15:08:29

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-19T09:59:14', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '476b2e2a-6947-44dd-ada7-387368deb944' User entered 'None (0)'	System	19 Oct 2020 15:08:29
	System	19 Oct 2020 15:08:29



US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-19T09:59:15', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '476b2e2a-6947-44dd-ada7-387368deb944' User entered 'None (0)'	System	19 Oct 2020 15:08:29
	System	19 Oct 2020 15:08:29

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-19T09:59:17', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '476b2e2a-6947-44dd-ada7-387368deb944' User entered 'None (0)'	System	19 Oct 2020 15:08:29
	System	19 Oct 2020 15:08:29

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-19T09:59:19', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '476b2e2a-6947-44dd-ada7-387368deb944'	System	19 Oct 2020 15:08:29
User entered 'No (N)'	System	19 Oct 2020 15:08:29

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-19T09:59:21', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '476b2e2a-6947-44dd-ada7-387368deb944' User entered '19 Oct 2020 09:59'	System	19 Oct 2020 15:08:29
	System	19 Oct 2020 15:08:29

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	14 Oct 2020 16:10:06
User entered 'Day 6'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-20T06:35:11', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0bdf63ef-b936-4d07-a435-2a91fb25cb1a' User entered 'None (0)'	System	20 Oct 2020 11:35:29
	System	20 Oct 2020 11:35:29



US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-20T06:35:13', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0bdf63ef-b936-4d07-a435-2a91fb25cb1a' User entered 'None (0)'	System	20 Oct 2020 11:35:29
	System	20 Oct 2020 11:35:29

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-20T06:35:15', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0bdf63ef-b936-4d07-a435-2a91fb25cb1a' User entered 'None (0)'	System	20 Oct 2020 11:35:29
	System	20 Oct 2020 11:35:29

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-20T06:35:18', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0bdf63ef-b936-4d07-a435-2a91fb25cb1a' User entered 'None (0)'	System	20 Oct 2020 11:35:29
	System	20 Oct 2020 11:35:29

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-20T06:35:19', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0bdf63ef-b936-4d07-a435-2a91fb25cb1a' User entered 'None (0)'	System	20 Oct 2020 11:35:29
	System	20 Oct 2020 11:35:29

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-20T06:35:22', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0bdf63ef-b936-4d07-a435-2a91fb25cb1a' User entered 'None (0)'	System	20 Oct 2020 11:35:29
	System	20 Oct 2020 11:35:29

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-20T06:35:24', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0bdf63ef-b936-4d07-a435-2a91fb25cb1a' User entered 'No (N)'	System	20 Oct 2020 11:35:29
	System	20 Oct 2020 11:35:29

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-20T06:35:27', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0bdf63ef-b936-4d07-a435-2a91fb25cb1a' User entered '20 Oct 2020 06:35'	System	20 Oct 2020 11:35:29
	System	20 Oct 2020 11:35:29

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 16:10:06



US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	14 Oct 2020 16:10:06
User entered 'Day 7'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-21T06:25:21', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '60dd79f2-cbec-4d4b-b255-5150b79a0f61' User entered 'None (0)'	System	21 Oct 2020 11:25:37
	System	21 Oct 2020 11:25:37

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-21T06:25:22', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '60dd79f2-cbec-4d4b-b255-5150b79a0f61' User entered 'None (0)'	System	21 Oct 2020 11:25:37
	System	21 Oct 2020 11:25:37

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-21T06:25:24', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '60dd79f2-cbec-4d4b-b255-5150b79a0f61' User entered 'None (0)'	System	21 Oct 2020 11:25:37
	System	21 Oct 2020 11:25:37

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-21T06:25:26', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '60dd79f2-cbec-4d4b-b255-5150b79a0f61' User entered 'None (0)'	System	21 Oct 2020 11:25:37
	System	21 Oct 2020 11:25:37

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-21T06:25:27', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '60dd79f2-cbec-4d4b-b255-5150b79a0f61' User entered 'None (0)'	System	21 Oct 2020 11:25:37
	System	21 Oct 2020 11:25:37

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-21T06:25:29', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '60dd79f2-cbec-4d4b-b255-5150b79a0f61' User entered 'None (0)'	System	21 Oct 2020 11:25:37
	System	21 Oct 2020 11:25:37



US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-21T06:25:31', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '60dd79f2-cbec-4d4b-b255-5150b79a0f61' User entered 'No (N)'	System	21 Oct 2020 11:25:37
	System	21 Oct 2020 11:25:37

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-10-21T06:25:34', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '60dd79f2-cbec-4d4b-b255-5150b79a0f61' User entered '21 Oct 2020 06:25'	System	21 Oct 2020 11:25:37
	System	21 Oct 2020 11:25:37

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 16:10:06

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 16:10:06

US3422281

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	22 Oct 2020 14:09:49

US3422281

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '22 Oct 2020'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	22 Oct 2020 14:09:49

US3422281

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cindy Trimmer (b) (4)	22 Oct 2020 14:09:49

US3422281

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	Cindy Trimmer (b) (4)	22 Oct 2020 14:09:49



US3422281

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	22 Oct 2020 14:09:57

US3422281

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'I'	System	22 Oct 2020 14:09:57

US3422281

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 21:17:14

US3422281

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '28 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:17:14

US3422281

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:17:14

US3422281

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:17:14

US3422281

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:17:20

**US3422281**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'I'	System	29 Oct 2020 21:17:20



**US3422281**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:21:42

US3422281

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '4 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:21:42

US3422281

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:21:42

US3422281

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:21:42

US3422281

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:21:30

**US3422281**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'I'	System	05 Nov 2020 19:21:30

US3422281

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	(b) (4) Cindy Trimmer (b) (4)	24 Nov 2020 19:13:02

US3422281

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 09:29:08
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'DATE CONFIRMED, PARTICIPANT UNABLE TO COMPLY, PROTOCOL DEVIATION COMPLETED.' (Site from System).	April Hanlotxomphou (b) (4)	04 Dec 2020 18:33:35
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	24 Nov 2020 19:13:02
User entered '24 Nov 2020'	Cindy Trimmer (b) (4) (b) (4)	24 Nov 2020 19:13:02



US3422281

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Clinic (Clinic)'	Cindy Trimmer (b) (4)	24 Nov 2020 19:13:02

**US3422281**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'VISIT3'	System	24 Nov 2020 19:13:02

US3422281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	28 Mar 2021 13:47:37
User entered 'No (N)'	(b) (4) Cindy Trimmer (b) (4)	24 Mar 2021 19:35:54

US3422281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	28 Mar 2021 13:47:37
User entered empty.	(b) (4) Cindy Trimmer (b) (4)	24 Mar 2021 19:35:54

US3422281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	28 Mar 2021 13:47:37
User entered empty.	Cindy Trimmer (b) (4)	24 Mar 2021 19:35:54

US3422281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered empty.	System	24 Mar 2021 19:35:54

US3422281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	28 Mar 2021 13:47:37
User entered empty.	(b) (4) Cindy Trimmer (b) (4)	24 Mar 2021 19:35:54
	(b) (4)	

US3422281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	28 Mar 2021 13:47:37
User entered empty.	Cindy Trimmer (b) (4)	24 Mar 2021 19:35:54



US3422281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	28 Mar 2021 13:47:37
User entered empty.	(b) (4) Cindy Trimmer (b) (4)	24 Mar 2021 19:35:54

US3422281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	28 Mar 2021 13:47:37
User entered empty.	(b) (4) Cindy Trimmer (b) (4)	24 Mar 2021 19:35:54

US3422281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered empty.	System	24 Mar 2021 19:35:54

US3422281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	28 Mar 2021 13:47:37
User entered empty.	(b) (4) Cindy Trimmer (b) (4)	24 Mar 2021 19:35:54

US3422281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered empty.	System	24 Mar 2021 19:35:54

US3422281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	28 Mar 2021 13:47:37
User entered empty.	(b) (4) Cindy Trimmer (b) (4)	24 Mar 2021 19:35:54

US3422281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered empty.	System	24 Mar 2021 19:35:54

US3422281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	28 Mar 2021 13:47:37
User entered empty.	(b) (4) Cindy Trimmer (b) (4)	24 Mar 2021 19:35:54



US3422281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered empty.	System	24 Mar 2021 19:35:54

US3422281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26

US3422281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26

US3422281

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'No (N)'	(b) (4) Cindy Trimmer (b) (4)	24 Nov 2020 19:13:42

US3422281

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered empty.	Cindy Trimmer (b) (4)	24 Nov 2020 19:13:42

US3422281

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	(b) (4) Cindy Trimmer (b) (4)	24 Nov 2020 19:13:55

US3422281

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '24 Nov 2020'	(b) (4) Cindy Trimmer (b) (4)	24 Nov 2020 19:13:55
	(b) (4)	

US3422281

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered '09:00'	(b) (4) Cindy Trimmer (b) (4)	24 Nov 2020 19:13:55



US3422281

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered '24 Nov 2020 09:00'	System	24 Nov 2020 19:13:55

US3422281

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 20:54:55
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	24 Nov 2020 19:13:58

**US3422281**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'I'	System	24 Nov 2020 19:13:58

US3422281

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	15 Sep 2020 16:09:26
User entered 'Day 64'	System	15 Sep 2020 16:09:26

US3422281

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-11-15T08:30:46', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '5ffc0c21-dbe8-4998-91d4-6263fca5e6b0'	System	15 Nov 2020 14:31:03
User entered 'No (N)'	System	15 Nov 2020 14:31:03

US3422281

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-11-15T08:30:51', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '5ffc0c21-dbe8-4998-91d4-6263fca5e6b0'	System	15 Nov 2020 14:31:03
User entered 'No (N)'	System	15 Nov 2020 14:31:03

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-11-15T08:30:59', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '5ffc0c21-dbe8-4998-91d4-6263fca5e6b0' User entered '15 Nov 2020 08:30:59'	System	15 Nov 2020 14:31:03
	System	15 Nov 2020 14:31:03

US3422281

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	15 Sep 2020 16:09:26
User entered '15 Nov 2020 00:01'	System	15 Sep 2020 16:09:26



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:54:32
Data entry locked.	System	15 Sep 2020 16:09:26
User entered '19 Nov 2020 23:59'	System	15 Sep 2020 16:09:26

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-11-26T06:44:58', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '223b6322-c208-4bfc-bd09-7f399f3ed01c' User entered 'No (N)'	System	26 Nov 2020 12:45:16
	System	26 Nov 2020 12:45:16

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Have you been exposed to someone with 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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-11-26T06:45:04', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '223b6322-c208-4bfc-bd09-7f399f3ed01c' User entered 'No (N)'	System	26 Nov 2020 12:45:16
	System	26 Nov 2020 12:45:16

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-11-26T06:45:11', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '223b6322-c208-4bfc-bd09-7f399f3ed01c' User entered '26 Nov 2020 06:45:11'	System	26 Nov 2020 12:45:16
	System	26 Nov 2020 12:45:16



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-12-05T12:00:16', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '272725cc-850b-49a1-a731-c85416366b0c' User entered 'No (N)'	System	05 Dec 2020 18:00:28
	System	05 Dec 2020 18:00:28

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Have you been exposed to someone with 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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-12-05T12:00:20', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '272725cc-850b-49a1-a731-c85416366b0c'	System	05 Dec 2020 18:00:28
User entered 'No (N)'	System	05 Dec 2020 18:00:28

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-12-05T12:00:24', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '272725cc-850b-49a1-a731-c85416366b0c' User entered '05 Dec 2020 12:00:24'	System	05 Dec 2020 18:00:28
	System	05 Dec 2020 18:00:28

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 08:38:09



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-12-11T07:12:27', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '7a570c67-0556-45cf-b339-fa27fcb80a50'	System	11 Dec 2020 13:12:40
User entered 'No (N)'	System	11 Dec 2020 13:12:40

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Have you been exposed to someone with 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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-12-11T07:12:34', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '7a570c67-0556-45cf-b339-fa27fcb80a50'	System	11 Dec 2020 13:12:40
User entered 'No (N)'	System	11 Dec 2020 13:12:40

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-12-11T07:12:38', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '7a570c67-0556-45cf-b339-fa27fcb80a50'	System	11 Dec 2020 13:12:40
User entered '11 Dec 2020 07:12:38'	System	11 Dec 2020 13:12:40

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-12-19T12:00:20', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0f53b62c-b52e-4397-b9bb-935c0d98dd6e'	System	19 Dec 2020 18:00:44
User entered 'No (N)'	System	19 Dec 2020 18:00:44



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Have you been exposed to someone with 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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-12-19T12:00:29', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0f53b62c-b52e-4397-b9bb-935c0d98dd6e'	System	19 Dec 2020 18:00:44
User entered 'No (N)'	System	19 Dec 2020 18:00:44

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-12-19T12:00:35', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0f53b62c-b52e-4397-b9bb-935c0d98dd6e' User entered '19 Dec 2020 12:00:35'	System	19 Dec 2020 18:00:44
	System	19 Dec 2020 18:00:44

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-12-24T07:12:28', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '975a21e9-7361-4bb2-b701-7220e7ffa41f' User entered 'No (N)'	System	24 Dec 2020 13:12:40
	System	24 Dec 2020 13:12:40

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Have you been exposed to someone with 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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-12-24T07:12:33', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '975a21e9-7361-4bb2-b701-7220e7ffa41f' User entered 'No (N)'	System	24 Dec 2020 13:12:40
	System	24 Dec 2020 13:12:40

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-12-24T07:12:37', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '975a21e9-7361-4bb2-b701-7220e7ffa41f' User entered '24 Dec 2020 07:12:37'	System	24 Dec 2020 13:12:40
	System	24 Dec 2020 13:12:40



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-12-31T06:35:59', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '041b20b9-5589-4dac-b855-fff92a23620d' User entered 'No (N)'	System	31 Dec 2020 12:36:13
	System	31 Dec 2020 12:36:13

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Have you been exposed to someone with 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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-12-31T06:36:06', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '041b20b9-5589-4dac-b855-fff92a23620d' User entered 'No (N)'	System	31 Dec 2020 12:36:13
	System	31 Dec 2020 12:36:13

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2020-12-31T06:36:10', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '041b20b9-5589-4dac-b855-fff92a23620d' User entered '31 Dec 2020 06:36:10'	System	31 Dec 2020 12:36:13
	System	31 Dec 2020 12:36:13

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 08:38:09



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-01-08T08:46:21', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'fb293f53-7911-44ff-b553-84c3e98b505e'	System	08 Jan 2021 14:46:33
User entered 'No (N)'	System	08 Jan 2021 14:46:33

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Have you been exposed to someone with 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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-01-08T08:46:25', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'fb293f53-7911-44ff-b553-84c3e98b505e'	System	08 Jan 2021 14:46:33
User entered 'No (N)'	System	08 Jan 2021 14:46:33

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-01-08T08:46:30', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'fb293f53-7911-44ff-b553-84c3e98b505e' User entered '08 Jan 2021 08:46:30'	System	08 Jan 2021 14:46:33
	System	08 Jan 2021 14:46:33

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-01-14T06:35:16', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'dd66d13b-0b55-4a95-b261-3ec2a29da270'	System	14 Jan 2021 12:35:37
User entered 'No (N)'	System	14 Jan 2021 12:35:37



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Have you been exposed to someone with 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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-01-14T06:35:21', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'dd66d13b-0b55-4a95-b261-3ec2a29da270'	System	14 Jan 2021 12:35:37
User entered 'No (N)'	System	14 Jan 2021 12:35:37

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-01-14T06:35:32', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'dd66d13b-0b55-4a95-b261-3ec2a29da270' User entered '14 Jan 2021 06:35:32'	System	14 Jan 2021 12:35:37
	System	14 Jan 2021 12:35:37

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-01-21T06:37:37', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '29d055a5-35df-4a8e-b53b-220b93c544ac' User entered 'No (N)'	System	21 Jan 2021 12:37:48
	System	21 Jan 2021 12:37:48

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Have you been exposed to someone with 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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-01-21T06:37:40', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '29d055a5-35df-4a8e-b53b-220b93c544ac'	System	21 Jan 2021 12:37:48
User entered 'No (N)'	System	21 Jan 2021 12:37:48

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-01-21T06:37:44', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '29d055a5-35df-4a8e-b53b-220b93c544ac' User entered '21 Jan 2021 06:37:44'	System	21 Jan 2021 12:37:48
	System	21 Jan 2021 12:37:48



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-01-28T11:43:13', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '2d333104-ccb1-4d1f-a02f-076e22107fd0'	System	28 Jan 2021 17:43:27
User entered 'No (N)'	System	28 Jan 2021 17:43:27

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Have you been exposed to someone with 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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-01-28T11:43:19', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '2d333104-ccb1-4d1f-a02f-076e22107fd0'	System	28 Jan 2021 17:43:27
User entered 'No (N)'	System	28 Jan 2021 17:43:27

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-01-28T11:43:25', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '2d333104-ccb1-4d1f-a02f-076e22107fd0' User entered '28 Jan 2021 11:43:25'	System	28 Jan 2021 17:43:27

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 08:38:09



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-02-04T18:01:31', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '22709fd1-c1ba-4750-a1cb-065fc6c15b5b' User entered 'No (N)'	System	05 Feb 2021 00:02:59
	System	05 Feb 2021 00:02:59

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Have you been exposed to someone with 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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-02-04T18:01:35', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '22709fd1-c1ba-4750-a1cb-065fc6c15b5b' User entered 'No (N)'	System	05 Feb 2021 00:02:59
	System	05 Feb 2021 00:02:59

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-02-04T18:01:40', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '22709fd1-c1ba-4750-a1cb-065fc6c15b5b' User entered '04 Feb 2021 18:01:40'	System	05 Feb 2021 00:02:59
	System	05 Feb 2021 00:02:59

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-02-11T07:18:31', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '149d2fd6-3aeb-450e-a7ab-e2e8374f94aa'	System	11 Feb 2021 12:18:46
User entered 'No (N)'	System	11 Feb 2021 12:18:46



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Have you been exposed to someone with 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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-02-11T07:18:27', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '149d2fd6-3aeb-450e-a7ab-e2e8374f94aa' User entered 'No (N)'	System	11 Feb 2021 12:18:46
	System	11 Feb 2021 12:18:46

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-02-11T07:18:43', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '149d2fd6-3aeb-450e-a7ab-e2e8374f94aa' User entered '11 Feb 2021 07:18:43'	System	11 Feb 2021 12:18:46
	System	11 Feb 2021 12:18:46

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-02-18T07:34:31', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '15c78c84-c44b-4781-9096-27ccefd6d1b' User entered 'No (N)'	System	18 Feb 2021 12:34:43
	System	18 Feb 2021 12:34:43

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Have you been exposed to someone with 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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-02-18T07:34:35', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '15c78c84-c44b-4781-9096-27ccefc6d1b' User entered 'No (N)'	System	18 Feb 2021 12:34:43
	System	18 Feb 2021 12:34:43

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-02-18T07:34:40', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '15c78c84-c44b-4781-9096-27ccefd6d1b' User entered '18 Feb 2021 07:34:40'	System	18 Feb 2021 12:34:43
	System	18 Feb 2021 12:34:43



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-02-25T11:54:07-05:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'fa781e49-1ddc-42a7-bc08-12fe71904666'	System	25 Feb 2021 18:21:47
User entered 'No (N)'	System	25 Feb 2021 18:21:47

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Have you been exposed to someone with 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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-02-25T11:54:15-05:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'fa781e49-1ddc-42a7-bc08-12fe71904666'	System	25 Feb 2021 18:21:47
User entered 'No (N)'	System	25 Feb 2021 18:21:47

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-02-25T11:54:19-05:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'fa781e49-1ddc-42a7-bc08-12fe71904666'	System	25 Feb 2021 18:21:47
User entered '25 Feb 2021 16:54:19'	System	25 Feb 2021 18:21:47

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 08:38:09



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-03-04T06:05:27-06:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '186e99a4-10b6-4d2d-a335-ef9c904e9843'	System	04 Mar 2021 12:05:38
User entered 'No (N)'	System	04 Mar 2021 12:05:38

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Have you been exposed to someone with 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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-03-04T06:05:29-06:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '186e99a4-10b6-4d2d-a335-ef9c904e9843'	System	04 Mar 2021 12:05:38
User entered 'No (N)'	System	04 Mar 2021 12:05:38

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-03-04T06:05:34-06:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '186e99a4-10b6-4d2d-a335-ef9c904e9843'	System	04 Mar 2021 12:05:38
User entered '04 Mar 2021 06:05:34'	System	04 Mar 2021 12:05:38

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-03-14T09:04:03-05:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'e8b7323a-60b2-451e-bce9-411c440d0367'	System	14 Mar 2021 14:04:28
User entered 'No (N)'	System	14 Mar 2021 14:04:28



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Have you been exposed to someone with 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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-03-14T09:04:06-05:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'e8b7323a-60b2-451e-bce9-411c440d0367'	System	14 Mar 2021 14:04:28
User entered 'No (N)'	System	14 Mar 2021 14:04:28

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-03-14T09:04:10-05:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'e8b7323a-60b2-451e-bce9-411c440d0367'	System	14 Mar 2021 14:04:28
User entered '14 Mar 2021 09:04:10'	System	14 Mar 2021 14:04:28

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-03-20T12:11:00-05:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '7a691402-7f11-467f-b509-d14debca4ddb' User entered 'No (N)'	System	20 Mar 2021 17:11:13
	System	20 Mar 2021 17:11:13

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Have you been exposed to someone with 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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-03-20T12:11:03-05:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '7a691402-7f11-467f-b509-d14debca4ddb' User entered 'No (N)'	System	20 Mar 2021 17:11:13
	System	20 Mar 2021 17:11:13

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-03-20T12:11:07-05:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '7a691402-7f11-467f-b509-d14debca4ddb' User entered '20 Mar 2021 12:11:07'	System	20 Mar 2021 17:11:13
	System	20 Mar 2021 17:11:13



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-03-25T06:12:42-05:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'ba551dd3-5555-4deb-b573-7ddc305793ee'	System	25 Mar 2021 11:12:53
User entered 'No (N)'	System	25 Mar 2021 11:12:53

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Have you been exposed to someone with 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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-03-25T06:12:46-05:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'ba551dd3-5555-4deb-b573-7ddc305793ee'	System	25 Mar 2021 11:12:53
User entered 'No (N)'	System	25 Mar 2021 11:12:53

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-03-25T06:12:49-05:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'ba551dd3-5555-4deb-b573-7ddc305793ee' User entered '25 Mar 2021 06:12:49'	System	25 Mar 2021 11:12:53
	System	25 Mar 2021 11:12:53

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 08:38:09



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-04-04T09:04:33-05:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '9f0a282c-d527-4714-a482-6e3de791614a' User entered 'No (N)'	System	04 Apr 2021 14:04:46
	System	04 Apr 2021 14:04:46

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Have you been exposed to someone with 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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-04-04T09:04:36-05:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '9f0a282c-d527-4714-a482-6e3de791614a' User entered 'No (N)'	System	04 Apr 2021 14:04:46
	System	04 Apr 2021 14:04:46

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-04-04T09:04:42-05:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '9f0a282c-d527-4714-a482-6e3de791614a' User entered '04 Apr 2021 09:04:42'	System	04 Apr 2021 14:04:46
	System	04 Apr 2021 14:04:46

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-04-10T12:03:50-05:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '448a123b-06a0-45de-9f92-3e5129ed18cf'	System	10 Apr 2021 17:05:37
User entered 'No (N)'	System	10 Apr 2021 17:05:37



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Have you been exposed to someone with 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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-04-10T12:03:53-05:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '448a123b-06a0-45de-9f92-3e5129ed18cf' User entered 'No (N)'	System	10 Apr 2021 17:05:37

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-04-10T12:03:57-05:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '448a123b-06a0-45de-9f92-3e5129ed18cf'	System	10 Apr 2021 17:05:37
User entered '10 Apr 2021 12:03:57'	System	10 Apr 2021 17:05:37

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-04-17T12:13:06-05:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'a8c2ecdb-1f89-4a75-85ac-581ebf851539'	System	18 Apr 2021 23:00:53
User entered 'No (N)'	System	18 Apr 2021 23:00:53

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Have you been exposed to someone with 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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-04-18T18:00:21-05:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'a8c2ecdb-1f89-4a75-85ac-581ebf851539'	System	18 Apr 2021 23:00:53
User entered 'No (N)'	System	18 Apr 2021 23:00:53

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-04-18T18:00:24-05:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: 'a8c2ecdb-1f89-4a75-85ac-581ebf851539'	System	18 Apr 2021 23:00:53
User entered '18 Apr 2021 18:00:24'	System	18 Apr 2021 23:00:53



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-04-22T06:16:01-05:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0de1ffa7-53ce-4116-a062-866af3af1aee' User entered 'No (N)'	System	22 Apr 2021 11:16:11
	System	22 Apr 2021 11:16:11

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Have you been exposed to someone with 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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-04-22T06:16:05-05:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0de1ffa7-53ce-4116-a062-866af3af1aee' User entered 'No (N)'	System	22 Apr 2021 11:16:11

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-04-22T06:16:08-05:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '0de1ffa7-53ce-4116-a062-866af3af1aee'	System	22 Apr 2021 11:16:11
User entered '22 Apr 2021 06:16:08'	System	22 Apr 2021 11:16:11

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 08:38:09



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-04-30T07:20:40-05:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '1248de4e-fa61-43b2-85b7-8cf5421b96b5' User entered 'No (N)'	System	30 Apr 2021 12:21:00
	System	30 Apr 2021 12:21:00

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

Have you been exposed to someone with 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 (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-04-30T07:20:46-05:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '1248de4e-fa61-43b2-85b7-8cf5421b96b5'	System	30 Apr 2021 12:21:00
User entered 'No (N)'	System	30 Apr 2021 12:21:00

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-04-30T07:20:51-05:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '1248de4e-fa61-43b2-85b7-8cf5421b96b5' User entered '30 Apr 2021 07:20:51'	System	30 Apr 2021 12:21:00
	System	30 Apr 2021 12:21:00

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 08:38:09



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 08:38:09



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 08:38:09



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 08:38:09



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 08:38:09



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 08:38:09



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 08:38:09



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 08:38:09



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 08:38:09



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 08:38:09



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 08:38:09



**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 08:38:09



**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 08:38:09



**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 08:38:09



**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 08:38:09



**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 08:38:09



**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 08:38:09



**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 08:38:09



**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 08:38:09



**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 08:38:09



**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 08:38:09



**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 08:38:09



**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 08:38:09



**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 08:38:09



**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 08:38:09



**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 08:38:09



**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 08:38:09



**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 08:38:09



**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 08:38:09



**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 08:38:09



**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 08:38:09

**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '17 Nov 2022 00:01'	System	20 Nov 2020 08:38:09



**US3422281**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered '21 Nov 2022 23:59'	System	20 Nov 2020 08:38:09

US3422281

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:34:58

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)	26 Apr 2021 03:23:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-03-04T06:05:39-06:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '20253368-1347-44aa-90f9-be82d7583ab3'	System	04 Mar 2021 12:05:46
User entered 'No (N)'	System	04 Mar 2021 12:05:46

US3422281

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:34:58

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 03:23:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C0934B40-8093-4FBE-947E-64D7924E72A0)', Time: '2021-03-04T06:05:43-06:00', User OID: 'PatientReportedOutcome (US3422281)', ODM File OID: '20253368-1347-44aa-90f9-be82d7583ab3' User entered '04 Mar 2021 06:05:43'	System	04 Mar 2021 12:05:46
	System	04 Mar 2021 12:05:46

US3422281

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	05 Mar 2021 19:00:01
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	11 Dec 2020 16:37:52

US3422281

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	05 Mar 2021 19:00:01
User entered '9 Dec 2020'	Cindy Trimmer (b) (4)	11 Dec 2020 16:37:52

US3422281

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	05 Mar 2021 19:00:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	11 Dec 2020 16:37:52

US3422281

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	05 Mar 2021 19:00:01
User entered empty.	(b) (4) Cindy Trimmer (b) (4)	11 Dec 2020 16:37:52
	(b) (4)	

US3422281

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User signature succeeded.	Clarence Creech (b) (4)	05 Mar 2021 19:00:01
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	11 Dec 2020 16:37:56



**US3422281**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:56:26
User entered 'I'	System	11 Dec 2020 16:37:56

**US3422281**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Jan 2021 21:32:04

US3422281

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:04

US3422281

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:04

US3422281

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:04

US3422281

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:31:53

**US3422281**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User entered 'I'	System	12 Jan 2021 21:31:53

**US3422281**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 20:26:38



US3422281

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 20:26:38

US3422281

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 20:26:38

US3422281

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 20:26:38

US3422281

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 20:26:27

**US3422281**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User entered 'I'	System	12 Feb 2021 20:26:27

**US3422281**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 17:35:14

US3422281

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:35:14

US3422281

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:35:14



US3422281

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:35:14

US3422281

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 17:34:58

**US3422281**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User entered 'I'	System	12 Mar 2021 17:34:58

US3422281

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:49:30

US3422281

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:49:30

US3422281

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:49:30

**US3422281**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User entered 'VISIT4'	System	29 Mar 2021 16:49:30

US3422281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'No (N)'	(b) (4) Cindy Trimmer (b) (4)	30 Mar 2021 17:30:07
	(b) (4)	



US3422281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered empty.	(b) (4) Cindy Trimmer (b) (4) (b) (4)	30 Mar 2021 17:30:07

US3422281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered empty.	(b) (4) Cindy Trimmer (b) (4)	30 Mar 2021 17:30:07

US3422281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User entered empty.	System	30 Mar 2021 17:30:07

US3422281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered empty.	(b) (4) Cindy Trimmer (b) (4)	30 Mar 2021 17:30:07
	(b) (4)	

US3422281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered empty.	Cindy Trimmer (b) (4)	30 Mar 2021 17:30:07

US3422281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered empty.	(b) (4) Cindy Trimmer (b) (4)	30 Mar 2021 17:30:07

US3422281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered empty.	(b) (4) Cindy Trimmer (b) (4) (b) (4)	30 Mar 2021 17:30:07

**US3422281**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User entered empty.	System	30 Mar 2021 17:30:07



US3422281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered empty.	(b) (4) Cindy Trimmer (b) (4)	30 Mar 2021 17:30:07
	(b) (4)	

US3422281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User entered empty.	System	30 Mar 2021 17:30:07

US3422281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered empty.	(b) (4) Cindy Trimmer (b) (4)	30 Mar 2021 17:30:07
	(b) (4)	

**US3422281**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:58**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User entered empty.	System	30 Mar 2021 17:30:07

US3422281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered empty.	(b) (4) Cindy Trimmer (b) (4)	30 Mar 2021 17:30:07
	(b) (4)	

US3422281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User entered empty.	System	30 Mar 2021 17:30:07

US3422281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	14 Apr 2021 06:59:15

US3422281

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	14 Apr 2021 06:59:15



US3422281

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:49:56

US3422281

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 16:49:56

US3422281

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:51:59

US3422281

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:51:59

**US3422281**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:34:58**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '09:05'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:51:59

**US3422281**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:34:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User entered '29 Mar 2021 09:05'	System	29 Mar 2021 16:51:59

US3422281

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:52:07

US3422281

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:59:15
User entered 'I'	System	29 Mar 2021 16:52:07



US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	12 Jan 2021 19:03:14

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '12 Jan 2021'	Cindy Trimmer (b) (4)	12 Jan 2021 19:03:14

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Clinic (Clinic)'	Cindy Trimmer (b) (4)	12 Jan 2021 19:03:14

**US3422281**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered 'UNBLND_DECIDE'	System	12 Jan 2021 19:03:14

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:34:58

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '06 Jan 2021'	Cindy Trimmer (b) (4)	12 Jan 2021 19:03:33

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:34:58

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	09 Apr 2021 03:01:02
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 02:43:16
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:26:23

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:34:58

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	12 Jan 2021 19:03:33

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:34:58

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 11:38:15
User signature succeeded.	Clarence Creech (b) (4)	09 Apr 2021 03:01:02
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 02:43:39
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	09 Apr 2021 02:43:16
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 19:16:24
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:26:23



US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:34:58

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '12 Jan 2021'	Cindy Trimmer (b) (4)	12 Jan 2021 19:03:33

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:34:58

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Placebo (Placebo)'	Cindy Trimmer (b) (4)	12 Jan 2021 19:03:33

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:34:58

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 15:02:03
User entered 'Placebo (Placebo)'	Cindy Trimmer (b) (4) (b) (4)	12 Jan 2021 19:03:33

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:34:58

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 15:02:03
User entered 'Placebo (Placebo)'	Cindy Trimmer (b) (4)	12 Jan 2021 19:03:33
	(b) (4)	

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:34:58

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	12 Jan 2021 19:03:33

**US3422281**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:34:58**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered '1'	System	12 Jan 2021 19:03:33

**US3422281**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:34:58**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered 'I'	System	12 Jan 2021 19:03:33

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered missing code ND - Not Done.	(b) (4) Cindy Trimmer (b) (4)	12 Jan 2021 19:05:05



US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered missing code ND - Not Done.	(b) (4) Cindy Trimmer (b) (4)	12 Jan 2021 19:05:05

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:58

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered empty.	System	12 Jan 2021 19:05:05
DataPoint set to visible.	System	12 Jan 2021 19:03:33

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered missing code ND - Not Done.	(b) (4) Cindy Trimmer (b) (4)	12 Jan 2021 19:05:05

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered missing code ND - Not Done.	(b) (4) Cindy Trimmer (b) (4)	12 Jan 2021 19:05:05

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:58

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered empty.	System	12 Jan 2021 19:05:05
DataPoint set to visible.	System	12 Jan 2021 19:03:33

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User accepted default value 'Pre-Dose (PREDOSE)'	Cindy Trimmer (b) (4) (b) (4)	12 Jan 2021 19:05:05

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Yes (Y)'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	12 Jan 2021 19:05:05

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '12 Jan 2021'	Cindy Trimmer (b) (4)	12 Jan 2021 19:05:05



US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '08:52'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	12 Jan 2021 19:05:05

**US3422281**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered '12 Jan 2021 08:52'	System	12 Jan 2021 19:05:05

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '98.0' F	Cindy Trimmer (b) (4)	12 Jan 2021 19:05:05

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Oral (Oral)'	Cindy Trimmer (b) (4)	12 Jan 2021 19:05:05

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered empty.	(b) (4) Cindy Trimmer (b) (4) (b) (4)	12 Jan 2021 19:05:05

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '086'	Cindy Trimmer (b) (4)	12 Jan 2021 19:05:05

**US3422281**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered 'bpm'	System	12 Jan 2021 19:05:05

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '014'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	12 Jan 2021 19:05:05



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered 'breaths/min'	System	12 Jan 2021 19:05:05

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '153'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	12 Jan 2021 19:05:05

**US3422281**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered 'mmHg'	System	12 Jan 2021 19:05:05

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '071'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	12 Jan 2021 19:05:05

**US3422281**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered 'mmHg'	System	12 Jan 2021 19:05:05

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered missing code ND - Not Done.	(b) (4) Cindy Trimmer (b) (4)	12 Jan 2021 19:05:05

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered missing code ND - Not Done.	(b) (4) Cindy Trimmer (b) (4)	12 Jan 2021 19:05:05

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:58

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered empty.	System	12 Jan 2021 19:05:05
DataPoint set to visible.	System	12 Jan 2021 19:03:33



US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User accepted default value 'Post-Dose (POSTDOSE)'	Cindy Trimmer (b) (4) (b) (4)	12 Jan 2021 19:05:05

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Yes (Y)'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	12 Jan 2021 19:05:05

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '12 Jan 2021'	(b) (4) Cindy Trimmer (b) (4)	12 Jan 2021 19:05:05

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '09:40'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	12 Jan 2021 19:05:05

**US3422281**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:34:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered '12 Jan 2021 09:40'	System	12 Jan 2021 19:05:05

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '98.1' F	Cindy Trimmer (b) (4)	12 Jan 2021 19:05:05

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Oral (Oral)'	Cindy Trimmer (b) (4)	12 Jan 2021 19:05:05

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered empty.	(b) (4) Cindy Trimmer (b) (4) (b) (4)	12 Jan 2021 19:05:05



US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '068'	Cindy Trimmer (b) (4)	12 Jan 2021 19:05:05

**US3422281**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:34:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered 'bpm'	System	12 Jan 2021 19:05:05

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '012'	Cindy Trimmer (b) (4)	12 Jan 2021 19:05:05

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered 'breaths/min'	System	12 Jan 2021 19:05:05

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '130'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	12 Jan 2021 19:05:05

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered 'mmHg'	System	12 Jan 2021 19:05:05

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '075'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	12 Jan 2021 19:05:05

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered 'mmHg'	System	12 Jan 2021 19:05:05



US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'No (N)'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	12 Jan 2021 19:05:36

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:58

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered empty.	Cindy Trimmer (b) (4)	12 Jan 2021 19:05:36

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	12 Jan 2021 19:06:04

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered empty.	Cindy Trimmer (b) (4)	12 Jan 2021 19:06:04

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

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)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered empty.	Cindy Trimmer (b) (4)	12 Jan 2021 19:06:04

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered 'mRNA-1273'	System	12 Jan 2021 19:06:04
DataPoint set to visible.	System	12 Jan 2021 19:03:33

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '12 Jan 2021'	Cindy Trimmer (b) (4)	12 Jan 2021 19:06:04

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '09:15'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	12 Jan 2021 19:06:04



**US3422281**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:34:58**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered '12 Jan 2021 09:15'	System	12 Jan 2021 19:06:04

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Cindy Trimmer (b) (4)	12 Jan 2021 19:06:04

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered 'ONCE'	System	12 Jan 2021 19:06:04

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered 'INTRAMUSCULAR'	System	12 Jan 2021 19:06:04

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	12 Jan 2021 19:06:46

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '12 Jan 2021'	Cindy Trimmer (b) (4)	12 Jan 2021 19:06:46

**US3422281**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:34:58**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '08:54'	Cindy Trimmer (b) (4)	12 Jan 2021 19:06:46

**US3422281**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:34:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered '12 Jan 2021 08:54'	System	12 Jan 2021 19:06:46



US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:34:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	12 Jan 2021 19:07:03

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:34:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '12 Jan 2021'	Cindy Trimmer (b) (4)	12 Jan 2021 19:07:03

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:34:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '08:57'	Cindy Trimmer (b) (4)	12 Jan 2021 19:07:03

**US3422281**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:34:58**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered '12 Jan 2021 08:57'	System	12 Jan 2021 19:07:03

US3422281

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	12 Jan 2021 19:07:08

**US3422281**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered '1'	System	12 Jan 2021 19:07:08

**US3422281**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	28 Mar 2021 13:47:37
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	20 Jan 2021 19:38:04

**US3422281**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:58**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	28 Mar 2021 13:47:37
User entered '20 Jan 2021'	Cindy Trimmer (b) (4)	20 Jan 2021 19:38:04



**US3422281**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	28 Mar 2021 13:47:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	20 Jan 2021 19:38:04

US3422281

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	28 Mar 2021 13:47:37
User entered empty.	(b) (4) Cindy Trimmer (b) (4) (b) (4)	20 Jan 2021 19:38:04

US3422281

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	28 Mar 2021 13:47:37
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	20 Jan 2021 19:38:08

**US3422281**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered 'I'	System	20 Jan 2021 19:38:08

**US3422281**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:58**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered 'I'	System	20 Jan 2021 19:38:08
DataPoint set to visible.	System	20 Jan 2021 19:38:08

US3422281

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Yes (Y)'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	08 Feb 2021 18:23:27

**US3422281**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:58**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '08 Feb 2021'	(b) (4) Cindy Trimmer (b) (4)	08 Feb 2021 18:23:27

US3422281

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:58

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Clinic (Clinic)'	Cindy Trimmer (b) (4)	08 Feb 2021 18:23:27



**US3422281**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User entered 'OLD29'	System	08 Feb 2021 18:23:27

US3422281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User accepted default value 'Pre-Dose (PREDOSE)'	Cindy Trimmer (b) (4) (b) (4)	08 Feb 2021 18:24:46

US3422281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Yes (Y)'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	08 Feb 2021 18:24:46

US3422281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '08 Feb 2021'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	08 Feb 2021 18:24:46

**US3422281**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:58**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '10:40'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	08 Feb 2021 18:24:46

**US3422281**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User entered '08 Feb 2021 10:40'	System	08 Feb 2021 18:24:46

US3422281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '97.8' F	Cindy Trimmer (b) (4)	08 Feb 2021 18:24:46

US3422281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Oral (Oral)'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	08 Feb 2021 18:24:46



US3422281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered empty.	(b) (4) Cindy Trimmer (b) (4) (b) (4)	08 Feb 2021 18:24:46

**US3422281**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '085'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	08 Feb 2021 18:24:46

US3422281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User entered 'bpm'	System	08 Feb 2021 18:24:46

US3422281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '018'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	08 Feb 2021 18:24:46

US3422281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User entered 'breaths/min'	System	08 Feb 2021 18:24:46

US3422281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '140'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	08 Feb 2021 18:24:46

**US3422281**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User entered 'mmHg'	System	08 Feb 2021 18:24:46

US3422281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '080'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	08 Feb 2021 18:24:46



US3422281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User entered 'mmHg'	System	08 Feb 2021 18:24:46

US3422281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User accepted default value 'Post-Dose (POSTDOSE)'	Cindy Trimmer (b) (4) (b) (4)	08 Feb 2021 18:24:46

US3422281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Yes (Y)'	(b) (4) Cindy Trimmer (b) (4)	08 Feb 2021 18:24:46

US3422281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '08 Feb 2021'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	08 Feb 2021 18:24:46

**US3422281**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:34:58**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '11:25'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	08 Feb 2021 18:24:46

**US3422281**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:34:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User entered '08 Feb 2021 11:25'	System	08 Feb 2021 18:24:46

US3422281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '98.2' F	Cindy Trimmer (b) (4)	08 Feb 2021 18:24:46

US3422281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Oral (Oral)'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	08 Feb 2021 18:24:46



US3422281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered empty.	(b) (4) Cindy Trimmer (b) (4) (b) (4)	08 Feb 2021 18:24:46

US3422281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '071'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	08 Feb 2021 18:24:46

**US3422281**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:34:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User entered 'bpm'	System	08 Feb 2021 18:24:46

US3422281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '014'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	08 Feb 2021 18:24:46

US3422281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User entered 'breaths/min'	System	08 Feb 2021 18:24:46

US3422281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '120'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	08 Feb 2021 18:24:46

US3422281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User entered 'mmHg'	System	08 Feb 2021 18:24:46

US3422281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '070'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	08 Feb 2021 18:24:46



US3422281

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User entered 'mmHg'	System	08 Feb 2021 18:24:46

**US3422281**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:34:58**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'No (N)'	(b) (4) Cindy Trimmer (b) (4)	08 Feb 2021 18:24:51

US3422281

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:58

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered empty.	Cindy Trimmer (b) (4)	08 Feb 2021 18:24:51

US3422281

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Yes (Y)'	(b) (4) Cindy Trimmer (b) (4)	08 Feb 2021 18:25:08

US3422281

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered empty.	Cindy Trimmer (b) (4)	08 Feb 2021 18:25:08

US3422281

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

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)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered empty.	(b) (4) Cindy Trimmer (b) (4) (b) (4)	08 Feb 2021 18:25:08

US3422281

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User entered 'mRNA-1273'	System	08 Feb 2021 18:25:08
DataPoint set to visible.	System	20 Jan 2021 19:38:08

US3422281

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '08 Feb 2021'	Cindy Trimmer (b) (4)	08 Feb 2021 18:25:08



US3422281

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '10:55'	(b) (4) Cindy Trimmer (b) (4)	08 Feb 2021 18:25:08

US3422281

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User entered '08 Feb 2021 10:55'	System	08 Feb 2021 18:25:08

US3422281

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	08 Feb 2021 18:25:08

US3422281

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User entered 'ONCE'	System	08 Feb 2021 18:25:08

US3422281

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User entered 'INTRAMUSCULAR'	System	08 Feb 2021 18:25:08

US3422281

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Yes (Y)'	(b) (4) Cindy Trimmer (b) (4)	08 Feb 2021 18:25:15

**US3422281**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User entered 'I'	System	08 Feb 2021 18:25:15

**US3422281**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	28 Mar 2021 13:47:37
User entered 'Yes (Y)'	(b) (4) Naomi Kown (b) (4)	16 Feb 2021 18:33:46



US3422281

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	28 Mar 2021 13:47:37
User entered '15 Feb 2021'	(b) (4) Naomi Kown (b) (4)	16 Feb 2021 18:33:46

**US3422281**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	28 Mar 2021 13:47:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Naomi Kown (b) (4) (b) (4)	16 Feb 2021 18:33:46

US3422281

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	28 Mar 2021 13:47:37
User entered empty.	(b) (4) Naomi Kown (b) (4) (b) (4)	16 Feb 2021 18:33:46

**US3422281**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:58**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	28 Mar 2021 13:47:37
User entered 'Yes (Y)'	(b) (4) Naomi Kown (b) (4)	16 Feb 2021 18:34:01

**US3422281**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered 'I'	System	16 Feb 2021 18:34:01

**US3422281**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:58**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:33:07

**US3422281**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:58**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '8 Mar 2021'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:33:07

**US3422281**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:58**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:33:07



**US3422281**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered 'OLD57'	System	08 Mar 2021 17:33:07

US3422281

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:33:50

US3422281

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '8 Mar 2021'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:33:50

**US3422281**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:58**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '11:00'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:33:50

**US3422281**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered '8 Mar 2021 11:00'	System	08 Mar 2021 17:33:50

**US3422281**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:58**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '097.5' F	(b) (4), (b) (6)	08 Mar 2021 17:33:50

US3422281

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:33:50

**US3422281**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:58**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:33:50



**US3422281**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:58**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '067'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:33:50

**US3422281**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered 'bpm'	System	08 Mar 2021 17:33:50

US3422281

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '14'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:33:50

US3422281

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered 'breaths/min'	System	08 Mar 2021 17:33:50

US3422281

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '124'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:33:50

**US3422281**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:58**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered 'mmHg'	System	08 Mar 2021 17:33:50

US3422281

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 11:15:06
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	08 Mar 2021 18:57:05
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		08 Mar 2021 17:33:50
User entered '055'	(b) (4), (b) (6)	08 Mar 2021 17:33:50

**US3422281**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:58**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00
User entered 'mmHg'	System	08 Mar 2021 17:33:50



US3422281

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00

US3422281

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:58

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:08:00

**US3422281**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:34:58**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:35:24

US3422281

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:58

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:35:24

US3422281

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:35:57

US3422281

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '8 Mar 2021'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:35:57

**US3422281**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:34:58**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '11:01'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:35:57

US3422281

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:57
User entered '8 Mar 2021 11:01'	System	08 Mar 2021 17:35:57



US3422281

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:34:58

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:46:28
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:34:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:14:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:29:57

US3422281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:58:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:19
User entered	System	02 Nov 2020 20:42:12
'USA-US082-2020-mRNA-1273-P301000003'		
User entered 'New'	(b) (4), (b) (6)	02 Nov 2020 20:42:12

US3422281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:35:19
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jan 2021 20:46:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jan 2021 20:46:47
User closed query 'Per CDM re-query: Please confirm if the Osteoarthritis worsened. If the condition worsened, please update the AE term to include the term "worsening" (eg: Worsening of osteoarthritis). Thank you' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 10:33:59
Data point term sent to Coder	System	27 Jan 2021 19:59:41
Query 'Per CDM re-query: Please confirm if the Osteoarthritis worsened. If the condition worsened, please update the AE term to include the term "worsening" (eg: Worsening of osteoarthritis). Thank you' answered with 'UPDATED' (Site from DM).	April Hanlotxomphou (b) (4)	27 Jan 2021 19:59:21
Coding entries removed.	April Hanlotxomphou (b) (4)	27 Jan 2021 19:59:12
User entered 'WORSENING OSTEOARTHRITIS' reason for change: Data Entry Error	April Hanlotxomphou (b) (4)	27 Jan 2021 19:59:12
User closed query 'Per DM CLR - RQ: Site's response "YES, WORSENING, SEE SERIOUS ADVERSE EVENT". If the condition worsen, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 04:14:01
User opened query 'Per CDM re-query: Please confirm if the Osteoarthritis worsened. If the condition worsened, please update the AE term to include the term "worsening" (eg: Worsening of osteoarthritis). Thank you' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 04:13:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	22 Dec 2020 18:58:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Dec 2020 18:58:46
Data point term sent to Coder	System	22 Dec 2020 18:57:54
User entered 'OSTEOARTHRITIS' reason for change: Data Entry Error	April Hanlotxomphou (b) (4)	22 Dec 2020 18:57:04
Query 'Per DM CLR - RQ: Site's response "YES, WORSENING, SEE SERIOUS ADVERSE EVENT". If the condition worsen, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.	April Hanlotxomphou (b) (4)	22 Dec 2020 18:54:16
' answered with 'UPDATED' (Site from DM).		
Data point term sent to Coder	System	22 Dec 2020 18:52:49
DataPoint Un-verified.	April Hanlotxomphou (b) (4)	22 Dec 2020 18:52:33
Coding entries removed.	April Hanlotxomphou (b) (4)	22 Dec 2020 18:52:33
User entered 'WORSENING OSTEOARTHRITIS' reason for change: Data Entry Error	April Hanlotxomphou (b) (4)	22 Dec 2020 18:52:33
User opened query 'Per DM CLR - RQ: Site's response "YES, WORSENING, SEE SERIOUS ADVERSE EVENT". If the condition worsen, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.	(b) (4), (b) (6)	20 Dec 2020 09:25:14
' (Site from DM).		
User closed query 'Please confirm, as per the query response, confirmed worsening condition. Should the SAE/AE term be updated to reflect this term? If so, please ensure to update source documents as well as EDC or clarify otherwise. ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 18:34:50

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Please confirm, as per the query response, confirmed worsening condition. Should the SAE/AE term be updated to reflect this term? If so, please ensure to update source documents as well as EDC or clarify otherwise. ' answered with 'condition was not worsened from baseline at enrollment. Participant had scheduled elective knee surgery in place' (Site from CRA).	Naomi Kown (b) (4)	23 Nov 2020 21:18:52
Query 'PV Query: Please update the SAE term to reflect 'worsening of osteoarthritis', as it was reported the event was a worsening of the preexisting generalized osteoarthritis. If to remain as osteoarthritis, please explain.' canceled (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 14:30:36
User opened query 'PV Query: Please update the SAE term to reflect 'worsening of osteoarthritis', as it was reported the event was a worsening of the preexisting generalized osteoarthritis. If to remain as osteoarthritis, please explain.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 14:30:18
User opened query 'Please confirm, as per the query response, confirmed worsening condition. Should the SAE/AE term be updated to reflect this term? If so, please ensure to update source documents as well as EDC or clarify otherwise. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:53:40
User closed query 'PV Query: Was this event of osteoarthritis considered a worsening of generalized osteoarthritis (pre-existing medical history). If so please, consider updating the event term to the condition (final diagnosis) that lead to the surgery (i.e., worsening of osteoarthritis). ' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 21:11:34
Query 'PV Query: Was this event of osteoarthritis considered a worsening of generalized osteoarthritis (pre-existing medical history). If so please, consider updating the event term to the condition (final diagnosis) that lead to the surgery (i.e., worsening of osteoarthritis). ' answered with 'YES, WORSENING, SEE SERIOUS ADVERSE EVENT.' (Site from Safety).	April Hanlotxomphou (b) (4)	13 Nov 2020 21:05:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Was this event of osteoarthritis considered a worsening of generalized osteoarthritis (pre-existing medical history). If so please, consider updating the event term to the condition (final diagnosis) that lead to the surgery (i.e., worsening of osteoarthritis). ' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 20:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:58:42
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:07:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:07:20
Data point term sent to Coder	System	30 Oct 2020 20:34:43
User entered 'osteoarthritis'	(b) (4), (b) (6)	30 Oct 2020 20:33:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:58:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:33:47

**US3422281**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:58:42
User entered 'No (N)'	(b) (4), (b) (6)	30 Oct 2020 20:33:47



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:58:42
User entered 'No (N)'	(b) (4), (b) (6)	30 Oct 2020 20:33:47

US3422281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:58:42
User entered '27 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 20:33:47

**US3422281**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:58:42
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:33:47

**US3422281**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:58**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 20:33:47

**US3422281**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:58:42
User entered 'No (N)'	(b) (4), (b) (6)	30 Oct 2020 20:33:47

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:58**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:58:42
User entered '28 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 20:33:47

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:58**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:58:42
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:33:47

**US3422281**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:58**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 20:33:47



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

Severity

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:58:42
User closed query 'PV Query: Since the subject was hospitalized for the event of osteoarthritis, appropriate CTCAE grade should be grade 3 instead of grade 1. Please update the event severity as such. If the severity is to remain grade 1/grade 2, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 15:08:53
Query 'PV Query: Since the subject was hospitalized for the event of osteoarthritis, appropriate CTCAE grade should be grade 3 instead of grade 1. Please update the event severity as such. If the severity is to remain grade 1/grade 2, please clarify/explain.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 21:12:50
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:12:43
User opened query 'PV Query: Since the subject was hospitalized for the event of osteoarthritis, appropriate CTCAE grade should be grade 3 instead of grade 1. Please update the event severity as such. If the severity is to remain grade 1/grade 2, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 19:51:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	30 Oct 2020 20:33:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:58:42
User closed query 'PV Query: Please confirm that this event met SAE criteria. Planned procedures for pre-existing conditions are not considered SAEs.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 15:08:57
Query 'PV Query: Please confirm that this event met SAE criteria. Planned procedures for pre-existing conditions are not considered SAEs.' answered with 'sae due to hospitalization ' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 21:13:09
User opened query 'PV Query: Please confirm that this event met SAE criteria. Planned procedures for pre-existing conditions are not considered SAEs.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 19:50:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:33:47

**US3422281**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:58:42
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 20:33:47

**US3422281**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:58:42
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 20:33:47

US3422281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:58:42
User entered 'I'	(b) (4), (b) (6)	30 Oct 2020 20:33:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:58:42
User entered '27 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 20:33:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:58:42
User entered '28 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 20:33:47

**US3422281**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:58:42
User entered 'No (N)'	(b) (4), (b) (6)	30 Oct 2020 20:33:47



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:58:42
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:33:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:58:42
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 20:33:47

US3422281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:58:42
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 20:33:47

**US3422281**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:58:42
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 20:33:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:58:42
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	30 Oct 2020 20:33:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:58:42
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	30 Oct 2020 20:33:47

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:58:42
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	30 Oct 2020 20:33:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

None

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:58:42
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 20:33:47



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:35:51
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM #3 indication is PAIN POST PROCEDURE. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 07:37:35
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM #3 indication is PAIN POST PROCEDURE. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' answered with 'corrected' (Site from DM).	Naomi Kown (b) (4) (b) (4)	19 Mar 2021 15:07:07
DataPoint Un-verified.	Naomi Kown (b) (4) (b) (4)	19 Mar 2021 15:06:57
User entered '0' reason for change: Data Entry Error	Naomi Kown (b) (4) (b) (4)	19 Mar 2021 15:06:57
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM #3 indication is PAIN POST PROCEDURE. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 01:01:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:58:42
User entered '1'	(b) (4), (b) (6)	30 Oct 2020 20:33:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Dec 2020 04:37:01
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'ONGOING USE OF MELOXICAM FOR OSTEOARTHRITIS RELIEF' (Site from DM).	April Hanlotxomphou (b) (4)	22 Dec 2020 18:53:37
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	20 Dec 2020 09:24:32
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:35:00
DataPoint Un-verified.	Naomi Kown (b) (4)	23 Nov 2020 21:17:51
User entered '1' reason for change: Data Entry Error	(b) (4) Naomi Kown (b) (4)	23 Nov 2020 21:17:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:58:42
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 20:33:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:58:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	30 Oct 2020 20:33:47

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Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:58:42
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:33:47

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 02:55:23
User closed query 'Please confirm if "elective" should be entered rather than "electric". If confirmed, please update or clarify otherwise. ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:55:21
Query 'Please confirm if "elective" should be entered rather than "electric". If confirmed, please update or clarify otherwise. ' answered with 'UPDATED' (Site from CRA).	April Hanlotxomphou (b) (4)	13 Nov 2020 21:06:50
DataPoint Un-verified.	April Hanlotxomphou (b) (4)	13 Nov 2020 21:06:40
User entered 'PARTICIPANT SCHEDULED FOR ELECTIVE LEFT TOTAL KNEE ARTHROPLASTY SPENT ONE EVENING INPATIENT.' reason for change: Data Entry Error	April Hanlotxomphou (b) (4)	13 Nov 2020 21:06:40
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:58:42
User opened query 'Please confirm if "elective" should be entered rather than "electric". If confirmed, please update or clarify otherwise. ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 19:22:40
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 15:09:06
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 15:09:01
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'added ' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 21:12:03

US3422281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:58

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 21:11:50
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 19:51:39
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 19:51:24
User entered 'participant scheduled for electric left total knee arthroplasty spent one evening inpatient.'	(b) (4), (b) (6)	30 Oct 2020 20:33:47

**US3422281**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 20:33:47

**US3422281**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 20:33:47



**US3422281**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Oct 2020 20:33:47

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:34:58

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:46:28
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:59:13
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:02:10

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:58:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 18:03:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 18:03:45
Data point term sent to Coder	System	15 Sep 2020 18:02:52
User entered 'Omeprazole'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:02:46

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:58:18
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:02:46

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:58:22
User entered 'acid reflux'	Cindy Trimmer (b) (4)	15 Sep 2020 18:02:46
	(b) (4)	

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:58:24
User entered '40'	Cindy Trimmer (b) (4)	15 Sep 2020 18:02:46
	(b) (4)	

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:58:26
User entered 'mg (mg)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:02:46

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:34:58**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:58:28
User entered empty.	Cindy Trimmer (b) (4)	15 Sep 2020 18:02:46
	(b) (4)	



US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:58:29
User entered 'once daily (QD)'	Cindy Trimmer (b) (4)	15 Sep 2020 18:02:46
	(b) (4)	

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:34:58**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:58:31
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:02:46

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:58:33
User entered 'Oral (ORAL)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:02:46

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:34:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:58:35
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:02:46

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:58:39
User entered 'un UNK 2008' reason for change: New Information	(b) (4), (b) (6)	14 Oct 2020 19:52:21
User entered '30 Jun 2008'	Cindy Trimmer (b) (4)	15 Sep 2020 18:02:46
	(b) (4)	

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:58:42
User entered '0'	Cindy Trimmer (b) (4)	15 Sep 2020 18:02:46
	(b) (4)	

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:58:46
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:02:46

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:58:48
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:02:46



US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:58:50
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:02:46

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 18:02:46

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 18:02:46

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 18:02:46

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:58

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 10:53:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 10:53:33
Data point term sent to Coder	System	28 Oct 2020 19:44:13
Coding entries removed.	April Hanlotxomphou (b) (4)	28 Oct 2020 19:43:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 18:04:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 18:04:50
Data point term sent to Coder	System	15 Sep 2020 18:03:53
User entered 'Meloxicam'	Cindy Trimmer (b) (4)	15 Sep 2020 18:03:27

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'No (N)'	Cindy Trimmer (b) (4)	15 Sep 2020 18:03:27
	(b) (4)	

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:15:37
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 04:48:20
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' answered with 'UPDATED' (Site from DM).	April Hanlotxomphou (b) (4)	28 Oct 2020 19:43:59
User entered 'OSTEO-ARTHRITIS, GENERALIZED' reason for change: Data Entry Error	April Hanlotxomphou (b) (4)	28 Oct 2020 19:43:51
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:22:06
User entered 'arthritis'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:03:27

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered '7.5'	Cindy Trimmer (b) (4)	15 Sep 2020 18:03:27
	(b) (4)	



US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'mg (mg)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:03:27

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:34:58**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered empty.	Cindy Trimmer (b) (4)	15 Sep 2020 18:03:27
	(b) (4)	

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'once daily (QD)'	Cindy Trimmer (b) (4)	15 Sep 2020 18:03:27
	(b) (4)	

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:34:58**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered empty.	Cindy Trimmer (b) (4)	15 Sep 2020 18:03:27
	(b) (4)	

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'Oral (ORAL)'	Cindy Trimmer (b) (4)	15 Sep 2020 18:03:27
	(b) (4)	

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:34:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered empty.	Cindy Trimmer (b) (4)	15 Sep 2020 18:03:27
	(b) (4)	

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'un May 2020' reason for change: New Information	(b) (4), (b) (6)	14 Oct 2020 19:52:49
User entered '15 May 2020'	Cindy Trimmer (b) (4)	15 Sep 2020 18:03:27
	(b) (4)	

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:34:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered '0'	Cindy Trimmer (b) (4)	15 Sep 2020 18:03:27
	(b) (4)	



US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	15 Sep 2020 18:03:27
	(b) (4)	

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:34:58**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered empty.	Cindy Trimmer (b) (4)	15 Sep 2020 18:03:27
	(b) (4)	

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:34:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'No (N)'	Cindy Trimmer (b) (4)	15 Sep 2020 18:03:27
	(b) (4)	

**US3422281**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:34:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 18:03:27

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:34:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 18:03:27

**US3422281**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:34:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 18:03:27

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:27:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 20:24:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 20:24:56
Data point term sent to Coder	System	30 Oct 2020 20:23:53
User entered 'dilaudid'	(b) (4), (b) (6)	30 Oct 2020 20:23:00

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:27:28
User entered 'No (N)'	(b) (4), (b) (6)	30 Oct 2020 20:23:00



US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:27:31
User entered 'pain post procedure'	(b) (4), (b) (6)	30 Oct 2020 20:23:00

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:27:33
User entered '4'	(b) (4), (b) (6)	30 Oct 2020 20:23:00

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:27:35
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Oct 2020 20:23:00

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:27:36
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:23:00

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:27:46
User entered 'as needed (PRN)'	(b) (4), (b) (6)	30 Oct 2020 20:23:00

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:27:48
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:23:00

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:27:49
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	30 Oct 2020 20:23:00

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:27:50
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:23:00



US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User closed query 'Per ETRTR: Please confirm start date for this and related Medications to SAE "Osteoarthritis" (Procedure dated 27Oct20), thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Nov 2020 21:01:56
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:27:53
Query 'Per ETRTR: Please confirm start date for this and related Medications to SAE "Osteoarthritis" (Procedure dated 27Oct20), thanks.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 19:38:29
User entered '27 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 19:38:08
User opened query 'Per ETRTR: Please confirm start date for this and related Medications to SAE "Osteoarthritis" (Procedure dated 27Oct20), thanks.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 19:10:03
User entered '26 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 20:23:00

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:27:55
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 20:23:00

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:15:37
User closed query 'Please confirm this is ongoing or if an end date is known.' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 21:02:02
Query 'Please confirm this is ongoing or if an end date is known.' answered with 'entered' (Site from CRA).	Naomi Kown (b) (4) (b) (4)	13 Nov 2020 21:51:27
DataPoint Un-verified.	Naomi Kown (b) (4) (b) (4)	13 Nov 2020 21:51:18
User entered 'No (N)' reason for change: Data Entry Error	Naomi Kown (b) (4) (b) (4)	13 Nov 2020 21:51:18
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:27:57
User opened query 'Please confirm this is ongoing or if an end date is known.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 22:26:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:23:00

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:15:37
DataPoint Un-verified.	Naomi Kown (b) (4)	13 Nov 2020 21:51:18
User entered '10 Nov 2020' reason for change: Data Entry Error	(b) (4) Naomi Kown (b) (4)	13 Nov 2020 21:51:18
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:27:58
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:23:00

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:05
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:28:00
User entered 'No (N)'	(b) (4), (b) (6)	30 Oct 2020 20:23:00

**US3422281**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:34:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:05
User entered empty.	System	30 Oct 2020 20:23:00

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:34:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:05
User entered empty.	System	30 Oct 2020 20:23:00

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:34:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:05
User entered empty.	System	30 Oct 2020 20:23:00



US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 22:29:21
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 20:26:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	30 Oct 2020 20:26:55
Data point term sent to Coder	System	30 Oct 2020 20:26:02
User entered 'xarelto'	(b) (4), (b) (6)	30 Oct 2020 20:25:44

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 22:29:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:25:44

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 22:29:24
User entered 'blood clot prevention'	(b) (4), (b) (6)	30 Oct 2020 20:25:44

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 22:29:30
User entered '10'	(b) (4), (b) (6)	30 Oct 2020 20:25:44

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 22:30:58
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Oct 2020 20:25:44

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:34:58**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 22:31:05
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:25:44

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	28 Feb 2021 18:10:37
User closed query 'Per DM CLR: Frequency = Once, however the Con Med is still ongoing. Please update the frequency on the CM eCRF page or provide an explanation.	(b) (4), (b) (6)	23 Dec 2020 04:16:07
' (Site from DM).		
Query 'Per DM CLR: Frequency = Once, however the Con Med is still ongoing. Please update the frequency on the CM eCRF page or provide an explanation.	April Hanlotxomphou (b) (4)	22 Dec 2020 18:57:57
' answered with 'UPDATED' (Site from DM).		
DataPoint Un-verified.	April Hanlotxomphou (b) (4)	22 Dec 2020 18:57:41
User entered 'once daily (QD)' reason for change: New Information	April Hanlotxomphou (b) (4)	22 Dec 2020 18:57:41
User opened query 'Per DM CLR: Frequency = Once, however the Con Med is still ongoing. Please update the frequency on the CM eCRF page or provide an explanation.	(b) (4), (b) (6)	15 Dec 2020 08:13:59
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:31:06
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 17:53:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 17:53:14
User entered 'once (ONCE)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 17:53:14
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 20:25:44
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:25:44

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 22:31:09
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:25:44



US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 22:31:10
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	30 Oct 2020 20:25:44

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:34:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 22:31:12
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:25:44

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 22:31:14
User entered '27 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 19:39:29
User entered '26 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 20:25:44

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:34:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 22:31:15
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 20:25:44

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User closed query 'Please confirm this medication is still ongoing. ' (Site from CRA).	(b) (4)	
Query 'Please confirm this medication is still ongoing. ' answered with 'yes, it is still ongoing' (Site from CRA).	(b) (4), (b) (6)	28 Feb 2021 18:10:43
User opened query 'Please confirm this medication is still ongoing. ' (Site from CRA).	Naomi Kown (b) (4)	24 Nov 2020 19:24:18
DataPoint Verified.	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 20:00:27
	(b) (4), (b) (6)	12 Nov 2020 22:31:17
	(b) (4), (b) (6)	30 Oct 2020 20:25:44

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:34:58**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 22:31:18
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:25:44

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 22:31:20
User entered 'No (N)'	(b) (4), (b) (6)	30 Oct 2020 20:25:44

**US3422281**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:34:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Dec 2020 18:57:41
User entered empty.	System	30 Oct 2020 20:25:44



**US3422281**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:34:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Dec 2020 18:57:41
User entered empty.	System	30 Oct 2020 20:25:44

**US3422281**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:34:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Dec 2020 18:57:41
User entered empty.	System	30 Oct 2020 20:25:44

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: BIOTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 21:14:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 21:14:28
Data point term sent to Coder	System	05 Nov 2020 21:13:13
User entered 'biotin'	(b) (4), (b) (6)	05 Nov 2020 21:13:08

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Feb 2021 18:10:59
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 04:16:14
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'UPDATED' (Site from DM).	April Hanlotxomphou (b) (4)	22 Dec 2020 18:58:50
DataPoint Un-verified.	April Hanlotxomphou (b) (4)	22 Dec 2020 18:58:44
User entered 'Yes (Y)' reason for change: Data Entry Error	April Hanlotxomphou (b) (4)	22 Dec 2020 18:58:44
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 08:09:52
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 21:13:08

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'health maintenance'	(b) (4), (b) (6)	05 Nov 2020 21:13:08

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered '1000'	(b) (4), (b) (6)	05 Nov 2020 21:13:08

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'ug (ug)'	(b) (4), (b) (6)	05 Nov 2020 21:13:08

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:34:58**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 21:13:08



US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'once daily (QD)'	(b) (4), (b) (6)	05 Nov 2020 21:13:08

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:34:58**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 21:13:08

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:34:58**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Nov 2020 21:13:08

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:34:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 21:13:08

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered '18 May 2020'	(b) (4), (b) (6)	05 Nov 2020 21:13:08

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:34:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 21:13:08

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 21:13:08

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:34:58**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 21:13:08



US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:34:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 21:13:08

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:34:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 21:13:08

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:34:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 21:13:08

**US3422281**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:34:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 21:13:08

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: CALCIUM COMPOUNDS, PRODUCT: CALCIUM CARBONATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Dec 2020 18:56:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:56:08
Data point term sent to Coder	System	08 Dec 2020 14:33:24
Data point term sent to Coder	System	08 Dec 2020 14:25:21
Coding entries removed.	Anna Gallion (b) (4)	08 Dec 2020 14:25:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:15:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: CALCIUM COMPOUNDS, PRODUCT: CALCIUM CARBONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 21:17:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 21:17:32
Data point term sent to Coder	System	05 Nov 2020 21:17:19
User entered 'calcium carbonate'	(b) (4), (b) (6)	05 Nov 2020 21:16:24

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 21:16:24

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
	(b) (4)	
User entered 'GERD (DUE TO OMEPRAZOLE USE), calcium deficiency' reason for change: Data Entry Error	Anna Gallion (b) (4)	08 Dec 2020 14:33:19
	(b) (4)	
DataPoint Un-verified.	Anna Gallion (b) (4)	08 Dec 2020 14:25:07
	(b) (4)	
User entered 'GERD (due to omeprazole use)' reason for change: Data Entry Error	Anna Gallion (b) (4)	08 Dec 2020 14:25:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'GERD'	(b) (4), (b) (6)	05 Nov 2020 21:16:24

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered '1000'	(b) (4), (b) (6)	05 Nov 2020 21:16:24



US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Nov 2020 21:16:24

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:34:58**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 21:16:24

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'as needed (PRN)'	(b) (4), (b) (6)	05 Nov 2020 21:16:24

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 21:16:24

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Nov 2020 21:16:24

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:34:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 21:16:24

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered '18 May 2020'	(b) (4), (b) (6)	05 Nov 2020 21:16:24

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:34:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 21:16:24



**US3422281**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:34:58**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 21:16:24

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 21:16:24

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 21:24:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 21:24:28
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 21:24:28
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 21:16:24
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 21:16:24

**US3422281**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:34:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 21:16:24

**US3422281**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:34:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 21:16:24

**US3422281**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:34:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 21:16:24

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MAGNESIUM CITRATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Dec 2020 03:39:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 03:39:46
Data point term sent to Coder	System	08 Dec 2020 14:23:20
Coding entries removed.	Anna Gallion (b) (4)	08 Dec 2020 14:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:15:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MAGNESIUM CITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:10:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:10:44
Data point term sent to Coder	System	05 Nov 2020 21:19:27
User entered 'magnesium citrate'	(b) (4), (b) (6)	05 Nov 2020 21:18:45

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 21:18:45



US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Feb 2021 18:11:20
User closed query 'Please confirm indication, as there is no AE noted and this is not for prophylactic treatment for 1 day. Did subject report Constipation Due to Pain Medications? If so, consider updating and adding an AE for this use. ' (Site from CRA).	(b) (4), (b) (6)	28 Feb 2021 18:11:18
DataPoint Un-verified.	Anna Gallion (b) (4)	08 Dec 2020 14:23:10
User entered 'LAXATIVE, (patient took for magnesium deficiency, but didn't mean to get the laxative)' reason for change: Data Entry Error	(b) (4) Anna Gallion (b) (4)	08 Dec 2020 14:23:10
Query 'Please confirm indication, as there is no AE noted and this is not for prophylactic treatment for 1 day. Did subject report Constipation Due to Pain Medications? If so, consider updating and adding an AE for this use. ' answered with 'Funny story: the patient accidentally took magnesium citrate, when she meant to take magnesium sulfate. I will correct in chart. ' (Site from CRA).	Anna Gallion (b) (4)	08 Dec 2020 14:19:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User opened query 'Please confirm indication, as there is no AE noted and this is not for prophylactic treatment for 1 day. Did subject report Constipation Due to Pain Medications? If so, consider updating and adding an AE for this use. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 20:09:25
User entered 'laxative'	(b) (4), (b) (6)	05 Nov 2020 21:18:45

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Feb 2021 18:11:23
DataPoint Un-verified.	Anna Gallion (b) (4)	08 Dec 2020 14:22:36
User entered '100' reason for change: Data Entry Error	(b) (4) Anna Gallion (b) (4)	08 Dec 2020 14:22:36
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered '296'	(b) (4), (b) (6)	05 Nov 2020 21:18:45

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Feb 2021 18:11:25
DataPoint Un-verified.	Anna Gallion (b) (4)	08 Dec 2020 14:22:36
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4) Anna Gallion (b) (4)	08 Dec 2020 14:22:36
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'mL (mL)'	(b) (4), (b) (6)	05 Nov 2020 21:18:45

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 21:18:45

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	05 Nov 2020 21:18:45

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 21:18:45

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Nov 2020 21:18:45

**US3422281**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:34:58**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 21:18:45



US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered '05 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 21:21:04
User entered empty; reason for change New Information	(b) (4), (b) (6)	05 Nov 2020 22:33:11
User entered '14 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 21:18:45

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:15:37
User closed query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	09 Nov 2020 21:21:12
User entered '0' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 21:21:12
User opened query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	09 Nov 2020 21:21:04
User entered '1' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 22:33:11
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 21:18:45

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 21:18:45

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:15:37
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	09 Nov 2020 21:21:04
User entered '05 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 21:21:04
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	05 Nov 2020 22:33:11
User entered empty; reason for change New Information	(b) (4), (b) (6)	05 Nov 2020 22:33:11
User entered '14 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 21:18:45

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:20
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 21:18:45

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:34:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:20
User entered empty.	System	05 Nov 2020 21:18:45

**US3422281**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:34:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:20
User entered empty.	System	05 Nov 2020 21:18:45

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:34:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:41:20
User entered empty.	System	05 Nov 2020 21:18:45



US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: VASOPROTECTIVES, ATC: CAPILLARY STABILIZING AGENTS, ATC: BIOFLAVONOIDS, PRODUCT: ASCORBIC ACID;BIOFLAVONOIDS NOS, PRODUCTSYNONYM: SUPER VITAMIN C - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	28 Dec 2020 19:36:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Dec 2020 19:36:22
Data point term sent to Coder	System	04 Dec 2020 19:49:41
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	04 Dec 2020 19:48:51
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'UPDATED' (Site from System).	April Hanlotxomphou (b) (4)	04 Dec 2020 19:48:51
DataPoint Un-verified.	April Hanlotxomphou (b) (4)	04 Dec 2020 19:48:45
User entered 'SUPER C COMPLEX, VITAMIN C AND BIOFLAVINOIDS' reason for change: Data Entry Error	April Hanlotxomphou (b) (4)	04 Dec 2020 19:48:45
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4) (b) (4)	23 Nov 2020 08:25:07
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:15:37
Data point term sent to Coder	System	05 Nov 2020 21:24:51

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EAB) (1725)

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:34:58**

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	05 Nov 2020 21:21:34
User entered 'super c complex'	(b) (4), (b) (6)	05 Nov 2020 21:21:30

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Dec 2020 07:36:51
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'UPDATED' (Site from DM).	April Hanlotxomphou (b) (4)	22 Dec 2020 18:59:25
DataPoint Un-verified.	April Hanlotxomphou (b) (4)	22 Dec 2020 18:59:19
User entered 'Yes (Y)' reason for change: Data Entry Error	April Hanlotxomphou (b) (4)	22 Dec 2020 18:59:19
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 08:11:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 21:21:30

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'health maintenance'	(b) (4), (b) (6)	05 Nov 2020 21:21:30

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Un-verified.	(b) (4)	
	April Hanlotxomphou	04 Dec 2020 19:48:45
	(b) (4)	
User entered '1000/500' reason for change: Data Entry Error	April Hanlotxomphou	04 Dec 2020 19:48:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered '400'	(b) (4), (b) (6)	05 Nov 2020 21:21:30

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Un-verified.	(b) (4)	
	April Hanlotxomphou	04 Dec 2020 19:48:45
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	April Hanlotxomphou	04 Dec 2020 19:48:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'ug (ug)'	(b) (4), (b) (6)	05 Nov 2020 21:21:30

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:34:58**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 21:21:30

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:38:11
User closed query 'Per DM CLR: Please verify the FREQUENCY of the dosage as 'Once' since the start and stop date duration is more than 1 day. Please update FREQUENCY or dates as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 08:54:03
Query 'Per DM CLR: Please verify the FREQUENCY of the dosage as 'Once' since the start and stop date duration is more than 1 day. Please update FREQUENCY or dates as appropriate.'	(b) (4), (b) (6)	07 Apr 2021 22:09:04
answered with 'updated' (Site from DM).		
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 22:08:50
Signature has been broken.		07 Apr 2021 22:08:50
User entered 'as needed (PRN)' reason for change: Data Entry Error		07 Apr 2021 22:08:50
User opened query 'Per DM CLR: Please verify the FREQUENCY of the dosage as 'Once' since the start and stop date duration is more than 1 day. Please update FREQUENCY or dates as appropriate.' (Site from DM).		07 Apr 2021 16:04:59
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	05 Nov 2020 21:21:30



US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 21:21:30

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 21:23:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 21:23:56
User entered 'Oral (ORAL)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 21:23:56
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 21:21:30
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 21:21:30

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:34:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 21:21:30

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:34:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered '05 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 15:00:55
User entered '14 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 21:21:30

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:34:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 21:21:30

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
	(b) (4)	
DataPoint Un-verified.	Anna Gallion (b) (4)	08 Dec 2020 14:29:07
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Anna Gallion (b) (4)	08 Dec 2020 14:29:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 21:21:30

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
	(b) (4)	
DataPoint Un-verified.	Anna Gallion (b) (4)	08 Dec 2020 14:29:07
	(b) (4)	
User entered empty; reason for change New Information	Anna Gallion (b) (4)	08 Dec 2020 14:29:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered '05 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 15:00:55
User entered '14 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 21:21:30

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:34:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 21:21:30



US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:34:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 21:21:30

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:34:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 21:21:30

**US3422281**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:34:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 21:21:30

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Dec 2020 03:38:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 03:38:45
Data point term sent to Coder	System	08 Dec 2020 14:34:26
Data point term sent to Coder	System	08 Dec 2020 14:31:23
User entered 'Magnesium'	Anna Gallion (b) (4) (b) (4)	08 Dec 2020 14:30:28
DataPoint activated with code reason code Data required.	Anna Gallion (b) (4) (b) (4)	08 Dec 2020 14:29:24
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4) (b) (4)	08 Dec 2020 14:23:28

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
	(b) (4)	
User entered 'No (N)'	Anna Gallion (b) (4)	08 Dec 2020 14:30:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Anna Gallion (b) (4)	08 Dec 2020 14:29:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4)	08 Dec 2020 14:23:28
	(b) (4)	

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'GERD (DUE TO OMEPRAZOLE USE), magnesium deficiency' reason for change: Data Entry Error	(b) (4)	
	Anna Gallion (b) (4)	08 Dec 2020 14:33:43
	(b) (4)	
User entered 'GERD (due to omeprazole use)'	Anna Gallion (b) (4)	08 Dec 2020 14:30:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Anna Gallion (b) (4)	08 Dec 2020 14:29:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4)	08 Dec 2020 14:23:28
	(b) (4)	

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
	(b) (4)	
User entered '500'	Anna Gallion (b) (4)	08 Dec 2020 14:30:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Anna Gallion (b) (4)	08 Dec 2020 14:29:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4)	08 Dec 2020 14:23:28
	(b) (4)	

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
	(b) (4)	
User entered 'mg (mg)'	Anna Gallion (b) (4)	08 Dec 2020 14:30:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Anna Gallion (b) (4)	08 Dec 2020 14:29:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4)	08 Dec 2020 14:23:28
	(b) (4)	



US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
	(b) (4)	
User entered empty.	Anna Gallion (b) (4)	08 Dec 2020 14:30:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Anna Gallion (b) (4)	08 Dec 2020 14:29:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4)	08 Dec 2020 14:23:28
	(b) (4)	

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
	(b) (4)	
User entered 'once daily (QD)'	Anna Gallion (b) (4)	08 Dec 2020 14:30:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Anna Gallion (b) (4)	08 Dec 2020 14:29:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4)	08 Dec 2020 14:23:28
	(b) (4)	

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:34:58**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
	(b) (4)	
User entered empty.	Anna Gallion (b) (4)	08 Dec 2020 14:30:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Anna Gallion (b) (4)	08 Dec 2020 14:29:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4)	08 Dec 2020 14:23:28
	(b) (4)	

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
	(b) (4)	
User entered 'Oral (ORAL)'	Anna Gallion (b) (4)	08 Dec 2020 14:30:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Anna Gallion (b) (4)	08 Dec 2020 14:29:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4)	08 Dec 2020 14:23:28
	(b) (4)	

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:34:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
	(b) (4)	
User entered empty.	Anna Gallion (b) (4)	08 Dec 2020 14:30:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Anna Gallion (b) (4)	08 Dec 2020 14:29:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4)	08 Dec 2020 14:23:28
	(b) (4)	

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
	(b) (4)	
User entered '18 May 2020'	Anna Gallion (b) (4)	08 Dec 2020 14:30:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Anna Gallion (b) (4)	08 Dec 2020 14:29:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4)	08 Dec 2020 14:23:28
	(b) (4)	

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
	(b) (4)	
User entered '0'	Anna Gallion (b) (4)	08 Dec 2020 14:30:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Anna Gallion (b) (4)	08 Dec 2020 14:29:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4)	08 Dec 2020 14:23:28
	(b) (4)	

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
	(b) (4)	
User entered 'Yes (Y)'	Anna Gallion (b) (4)	08 Dec 2020 14:30:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Anna Gallion (b) (4)	08 Dec 2020 14:29:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4)	08 Dec 2020 14:23:28
	(b) (4)	



US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
	(b) (4)	
User entered empty.	Anna Gallion (b) (4)	08 Dec 2020 14:30:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Anna Gallion (b) (4)	08 Dec 2020 14:29:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4)	08 Dec 2020 14:23:28
	(b) (4)	

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
	(b) (4)	
User entered 'No (N)'	Anna Gallion (b) (4)	08 Dec 2020 14:30:28
	(b) (4)	
DataPoint activated with code reason code Data required.	Anna Gallion (b) (4)	08 Dec 2020 14:29:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4)	08 Dec 2020 14:23:28
	(b) (4)	

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:34:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 14:30:28
DataPoint activated with code reason code Data required.	Anna Gallion (b) (4)	08 Dec 2020 14:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Anna Gallion (b) (4)	08 Dec 2020 14:23:28
	(b) (4)	

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:34:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Dec 2020 14:30:28
DataPoint activated with code reason code Data required.	Anna Gallion (b) (4) (b) (4)	08 Dec 2020 14:29:24
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4) (b) (4)	08 Dec 2020 14:23:28

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:34:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Dec 2020 14:30:28
DataPoint activated with code reason code Data required.	Anna Gallion (b) (4) (b) (4)	08 Dec 2020 14:29:24
DataPoint inactivated with code reason code Data not required.	Anna Gallion (b) (4) (b) (4)	08 Dec 2020 14:23:28

US3422281

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:34:58

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:46:28
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:03:08
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	29 Oct 2020 21:14:54
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:04:59

US3422281

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:32:17
User entered '27 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 21:16:05

US3422281

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:34:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:12:32
User closed query 'Please ensure to split term out, ie, "Primary Left Total Knee Arthroplasty". ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:12:30
Query 'Please ensure to split term out, ie, "Primary Left Total Knee Arthroplasty". ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 21:37:16
DataPoint Un-verified.		18 Nov 2020 21:37:11
User entered 'PRIMARY LEFT TOTAL KNEE ARTHROPLASTY' reason for change: New Information		18 Nov 2020 21:37:11
DataPoint Verified.		12 Nov 2020 21:32:15
User opened query 'Please ensure to split term out, ie "Primary Left Total Knee Arthroplasty". ' (Site from CRA).		12 Nov 2020 21:31:56
User entered 'primaryLEFT total KNEE arthroplasty' reason for change: New Information		30 Oct 2020 20:27:34
User entered 'left knee replacement'		29 Oct 2020 21:16:05



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:34:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:32:13
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	30 Oct 2020 20:29:28
User entered 'Adverse Event (AE)' reason for change: New Information	(b) (4), (b) (6)	30 Oct 2020 20:29:28
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	29 Oct 2020 21:16:05
User entered 'Medical History (MH)'	(b) (4), (b) (6)	29 Oct 2020 21:16:05

US3422281

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 17:34:58**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:32:12
User entered empty; reason for change New Information	(b) (4), (b) (6)	30 Oct 2020 20:29:28
User entered 'generalized osteo-arthritis'	(b) (4), (b) (6)	29 Oct 2020 21:16:05

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered	System	02 Nov 2020 20:42:12
'USA-US082-2020-MRNA-1273-P301000003'		

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Yes (Y)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Yes (Y)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12



**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

US3422281

Folder: SAE USA-US082-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Clarence'	System	02 Nov 2020 20:42:12

US3422281

Folder: SAE USA-US082-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Creech'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'CCC-5311 MCN'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Nashville'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'TN'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered '37027'	System	02 Nov 2020 20:42:12



**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:11:42
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:59:07
User entered 'US'	System	02 Nov 2020 20:43:14

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	22 Mar 2021 16:35:21
User entered '6'	System	28 Jan 2021 17:46:36
User entered '5'	System	22 Dec 2020 21:02:33
User entered '4'	System	24 Nov 2020 21:08:10
User entered '3'	System	16 Nov 2020 21:11:52
User entered '2'	System	10 Nov 2020 14:48:15
User entered '1'	System	02 Nov 2020 20:43:14

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered		
'USA-US082-2020-MRNA-1273-P301000003'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Yes (Y)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Yes (Y)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12



**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Clarence'	System	02 Nov 2020 20:42:12

US3422281

Folder: SAE USA-US082-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Creech'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'CCC-5311 MCN'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Nashville'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'TN'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered '37027'	System	02 Nov 2020 20:42:12



US3422281

Folder: SAE USA-US082-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:11:42
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:59:07
User entered 'US'	System	02 Nov 2020 20:43:14

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	22 Mar 2021 16:35:21
User entered '6'	System	28 Jan 2021 17:46:36
User entered '5'	System	22 Dec 2020 21:02:33
User entered '4'	System	24 Nov 2020 21:08:10
User entered '3'	System	16 Nov 2020 21:11:52
User entered '2'	System	10 Nov 2020 14:48:15
User entered '1'	System	02 Nov 2020 20:43:14

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:34:58**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:59:07
User entered '02/Nov/2020 20:43'	System	02 Nov 2020 20:43:14

US3422281

Folder: SAE USA-US082-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:34:58

**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.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:11:42
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:59:07
User entered 'I'	(b) (4), (b) (6)	02 Nov 2020 20:43:14

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered	System	02 Nov 2020 20:42:12
'USA-US082-2020-MRNA-1273-P301000003'		

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Yes (Y)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12



**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Yes (Y)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

US3422281

Folder: SAE USA-US082-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Clarence'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Creech'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'CCC-5311 MCN'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Nashville'	System	02 Nov 2020 20:42:12



**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'TN'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered '37027'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:11:42
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:59:07
User entered 'US'	System	02 Nov 2020 20:43:14

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	22 Mar 2021 16:35:21
User entered '6'	System	28 Jan 2021 17:46:36
User entered '5'	System	22 Dec 2020 21:02:33
User entered '4'	System	24 Nov 2020 21:08:10
User entered '3'	System	16 Nov 2020 21:11:52
User entered '2'	System	10 Nov 2020 14:48:15
User entered '1'	System	02 Nov 2020 20:43:14

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:34:58**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:59:07
User entered '10/Nov/2020 09:48'	System	10 Nov 2020 14:48:15

US3422281

Folder: SAE USA-US082-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:34:58

**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.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:11:42
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:59:07
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 14:48:15

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered	System	02 Nov 2020 20:42:12
'USA-US082-2020-MRNA-1273-P301000003'		

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Yes (Y)'	System	02 Nov 2020 20:42:12



**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Yes (Y)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

US3422281

Folder: SAE USA-US082-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Clarence'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Creech'	System	02 Nov 2020 20:42:12



**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'CCC-5311 MCN'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Nashville'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'TN'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered '37027'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:11:42
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:59:07
User entered 'US'	System	02 Nov 2020 20:43:14

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	22 Mar 2021 16:35:21
User entered '6'	System	28 Jan 2021 17:46:36
User entered '5'	System	22 Dec 2020 21:02:33
User entered '4'	System	24 Nov 2020 21:08:10
User entered '3'	System	16 Nov 2020 21:11:52
User entered '2'	System	10 Nov 2020 14:48:15
User entered '1'	System	02 Nov 2020 20:43:14

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:34:58**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:11:50
User entered '16/Nov/2020 21:11'	System	16 Nov 2020 21:11:52

US3422281

Folder: SAE USA-US082-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:34:58

**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.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 21:07:59
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:11:53
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 21:11:52



**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered		
'USA-US082-2020-MRNA-1273-P301000003'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Yes (Y)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Yes (Y)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12



US3422281

Folder: SAE USA-US082-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Clarence'	System	02 Nov 2020 20:42:12

US3422281

Folder: SAE USA-US082-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Creech'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'CCC-5311 MCN'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Nashville'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'TN'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered '37027'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:11:42
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:59:07
User entered 'US'	System	02 Nov 2020 20:43:14

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	22 Mar 2021 16:35:21
User entered '6'	System	28 Jan 2021 17:46:36
User entered '5'	System	22 Dec 2020 21:02:33
User entered '4'	System	24 Nov 2020 21:08:10
User entered '3'	System	16 Nov 2020 21:11:52
User entered '2'	System	10 Nov 2020 14:48:15
User entered '1'	System	02 Nov 2020 20:43:14



**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:34:58**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:36:06
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '24/Nov/2020 16:08'	(b) (4) System	24 Nov 2020 21:08:10

US3422281

Folder: SAE USA-US082-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:34:58

**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)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:36:08
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:02:20
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 21:08:10

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered		
'USA-US082-2020-MRNA-1273-P301000003'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Yes (Y)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Yes (Y)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12



**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Clarence'	System	02 Nov 2020 20:42:12

US3422281

Folder: SAE USA-US082-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Creech'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'CCC-5311 MCN'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Nashville'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'TN'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered '37027'	System	02 Nov 2020 20:42:12



**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:11:42
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:59:07
User entered 'US'	System	02 Nov 2020 20:43:14

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	22 Mar 2021 16:35:21
User entered '6'	System	28 Jan 2021 17:46:36
User entered '5'	System	22 Dec 2020 21:02:33
User entered '4'	System	24 Nov 2020 21:08:10
User entered '3'	System	16 Nov 2020 21:11:52
User entered '2'	System	10 Nov 2020 14:48:15
User entered '1'	System	02 Nov 2020 20:43:14

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 17:34:58**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:36:25
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '22/Dec/2020 16:02'	(b) (4) System	22 Dec 2020 21:02:33

US3422281

Folder: SAE USA-US082-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:34:58

**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)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:36:35
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:02:39
User entered 'I'	(b) (4), (b) (6)	22 Dec 2020 21:02:33

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered	System	02 Nov 2020 20:42:12
'USA-US082-2020-MRNA-1273-P301000003'		

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Yes (Y)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12



**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Yes (Y)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Clarence'	System	02 Nov 2020 20:42:12

US3422281

Folder: SAE USA-US082-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Creech'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'CCC-5311 MCN'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Nashville'	System	02 Nov 2020 20:42:12



**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'TN'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered '37027'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:11:42
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:59:07
User entered 'US'	System	02 Nov 2020 20:43:14

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	22 Mar 2021 16:35:21
User entered '6'	System	28 Jan 2021 17:46:36
User entered '5'	System	22 Dec 2020 21:02:33
User entered '4'	System	24 Nov 2020 21:08:10
User entered '3'	System	16 Nov 2020 21:11:52
User entered '2'	System	10 Nov 2020 14:48:15
User entered '1'	System	02 Nov 2020 20:43:14

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 17:34:58**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:36:17
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '28/Jan/2021 12:46'	(b) (4) System	28 Jan 2021 17:46:36

US3422281

Folder: SAE USA-US082-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:34:58

**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)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:36:19
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:35:04
User entered 'I'	(b) (4), (b) (6)	28 Jan 2021 17:46:36

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered	System	02 Nov 2020 20:42:12
'USA-US082-2020-MRNA-1273-P301000003'		

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Yes (Y)'	System	02 Nov 2020 20:42:12



**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Yes (Y)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'No (N)'	System	02 Nov 2020 20:42:12

US3422281

Folder: SAE USA-US082-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Clarence'	System	02 Nov 2020 20:42:12

US3422281

Folder: SAE USA-US082-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Creech'	System	02 Nov 2020 20:42:12



**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'CCC-5311 MCN'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'Nashville'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered 'TN'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 21:59:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 20:42:50
User entered '37027'	System	02 Nov 2020 20:42:12

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 21:11:42
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:59:07
User entered 'US'	System	02 Nov 2020 20:43:14

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:58**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	22 Mar 2021 16:35:21
User entered '6'	System	28 Jan 2021 17:46:36
User entered '5'	System	22 Dec 2020 21:02:33
User entered '4'	System	24 Nov 2020 21:08:10
User entered '3'	System	16 Nov 2020 21:11:52
User entered '2'	System	10 Nov 2020 14:48:15
User entered '1'	System	02 Nov 2020 20:43:14

**US3422281**

**Folder: SAE USA-US082-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (7)**

**Generated On: 09 Jun 2021 17:34:58**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:36:46
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered '22/Mar/2021 12:35'	(b) (4) System	22 Mar 2021 16:35:21

US3422281

Folder: SAE USA-US082-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:34:58

**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)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:36:48
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:29:01
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:35:21