

US3422281 (Prod: Vanderbilt University Medical Center)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:24:23

All time stamps listed in this document are displayed in GMT

**US3422281**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 09:24:23**

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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

Generated On: 26 Nov 2020 09:24:23

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

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:23

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

US3422281

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:23

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

Generated On: 26 Nov 2020 09:24:23

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:24:23

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:23

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)

Generated On: 26 Nov 2020 09:24:23

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="checkbox"/> 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)

Generated On: 26 Nov 2020 09:24:23

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)

Generated On: 26 Nov 2020 09:24:23

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)

Generated On: 26 Nov 2020 09:24:23

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

US3422281

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:24:23

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: Vital Signs

Generated On: 26 Nov 2020 09:24:23

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

Generated On: 26 Nov 2020 09:24:23

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

Generated On: 26 Nov 2020 09:24:23

Date of assessment ( <i>dd MMM yyyy</i> )	15 SEP 2020
Is the participant of childbearing potential?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If No, what is the reason?	Surgically sterile <input type="radio"/>
	Post-menopausal <input checked="" type="radio"/>
	Partner medically sterile <input type="radio"/>
	Not reached age of Menarche <input type="radio"/>
	Other <input type="radio"/>
If Partner medically sterile or Other, specify _____	
If Surgically sterile, date of surgery ( <i>dd MMM yyyy</i> ) _____	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation ( <i>dd MMM yyyy</i> )	UN UNK 2000
Date of last menstruation unknown	False



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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:23

**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

**Specify**

FREQUENTLY IN CROWDED  
PUBLIC AREAS MULTIPLE  
TIMES PER WEEK

**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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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:23

<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

Generated On: 26 Nov 2020 09:24:23

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

US3422281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:23

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 ☒

**US3422281**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 26 Nov 2020 09:24:23**

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:23

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)

Generated On: 26 Nov 2020 09:24:23

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

Generated On: 26 Nov 2020 09:24:23

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

Generated On: 26 Nov 2020 09:24:23

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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 <input type="radio"/>
	Right Arm <input checked="" type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3422281

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	15 SEP 2020
Collection time ( <i>00:00-23:59</i> )	10:33 (24 HR)
Collection date and time (derived)	15 SEP 2020 10:33

US3422281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:24:23

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		

US3422281

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:24:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:24:23

**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

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:24:23

**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

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:24:23

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**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: 26 Nov 2020 09:24:23

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**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: 26 Nov 2020 09:24:23

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 26 Nov 2020 09:24:23

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 26 Nov 2020 09:24:23

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**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: 26 Nov 2020 09:24:23

---

**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

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US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23

**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 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:24:23

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

Generated On: 26 Nov 2020 09:24:23

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

Generated On: 26 Nov 2020 09:24:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422281

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:23

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

Generated On: 26 Nov 2020 09:24:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3422281

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:23

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

Generated On: 26 Nov 2020 09:24:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422281

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:23

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)

Generated On: 26 Nov 2020 09:24:23

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)

Generated On: 26 Nov 2020 09:24:23

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 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="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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

Generated On: 26 Nov 2020 09:24:23

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

Generated On: 26 Nov 2020 09:24:23

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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 <input type="radio"/>
	Right Arm <input checked="" type="radio"/>
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

Generated On: 26 Nov 2020 09:24:23

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

Generated On: 26 Nov 2020 09:24:23

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

Generated On: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

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**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: 26 Nov 2020 09:24:23

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**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

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US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:24:23

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

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: 26 Nov 2020 09:24:23

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

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

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US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:24:23

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**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: 26 Nov 2020 09:24:23

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**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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23

**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 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23

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

Generated On: 26 Nov 2020 09:24:23

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

Generated On: 26 Nov 2020 09:24:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422281

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:23

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

Generated On: 26 Nov 2020 09:24:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422281

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:23

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

Generated On: 26 Nov 2020 09:24:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3422281

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:23

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

Generated On: 26 Nov 2020 09:24:23

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	
Vital Signs Date and Time (derived)	
Temperature ( <i>xxx.x</i> )	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse ( <i>xxx</i> )	
Pulse units	
Respiratory Rate ( <i>xxx</i> )	
Respiratory Rate units	
Systolic Blood Pressure ( <i>xxx</i> )	
Systolic Blood Pressure units	
Diastolic Blood Pressure ( <i>xxx</i> )	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3422281

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:23

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

Generated On: 26 Nov 2020 09:24:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	24 NOV 2020
Collection time ( <i>00:00-23:59</i> )	09:00 (24 HR)
Collection date and time (derived)	24 NOV 2020 09:00

US3422281

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 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: 26 Nov 2020 09:24:23

TIMEPOINT	DAY 61
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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 NOV 2020 23:59



US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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="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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	19 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 NOV 2020 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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 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: 26 Nov 2020 09:24:23**

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

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[Patient Cloud Close Date & Time](#)

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30 NOV 2020 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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: 26 Nov 2020 09:24:23**

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

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[Patient Cloud Close Date & Time](#)

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07 DEC 2020 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 DEC 2020 23:59



US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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 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: 26 Nov 2020 09:24:23**

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

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[Patient Cloud Close Date & Time](#)

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21 DEC 2020 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	24 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 DEC 2020 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

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

31 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 09:24:23**

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



US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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 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: 26 Nov 2020 09:24:23**

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

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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 <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: 26 Nov 2020 09:24:23**

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

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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: 26 Nov 2020 09:24:23**

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

28 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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: 26 Nov 2020 09:24:23**

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



US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 09:24:23**

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

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: 26 Nov 2020 09:24:23

**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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:24:23**

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

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[Patient Cloud Close Date & Time](#)

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22 FEB 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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 <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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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25 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAR 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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 <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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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04 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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 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: 26 Nov 2020 09:24:23**

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

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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 <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: 26 Nov 2020 09:24:23**

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

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: 26 Nov 2020 09:24:23

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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: 26 Nov 2020 09:24:23**

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

25 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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: 26 Nov 2020 09:24:23**

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

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01 APR 2021 00:01

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05 APR 2021 23:59



US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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 <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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 APR 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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15 APR 2021 00:01

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19 APR 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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: 26 Nov 2020 09:24:23**

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

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 09:24:23**

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

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[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23**

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

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[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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="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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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13 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23**

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

20 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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 <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: 26 Nov 2020 09:24:23**

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

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[Patient Cloud Close Date & Time](#)

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31 MAY 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23**

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

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[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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="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: 26 Nov 2020 09:24:23**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 09:24:23**

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

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23**

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

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[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

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

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

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

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[Patient Cloud Open Date & Time](#)

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08 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 JUL 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

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

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

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

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23**

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

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59



US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	26 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23**

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



US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

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

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[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

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="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: 26 Nov 2020 09:24:23**

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

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

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

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

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



US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 09:24:23**

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

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[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23**

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

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[Patient Cloud Close Date & Time](#)

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20 DEC 2021 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23**

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

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[Patient Cloud Open Date & Time](#)

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30 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 JAN 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 09:24:23**

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



US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23**

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

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 JAN 2022 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 FEB 2022 23:59



US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

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

17 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	24 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 FEB 2022 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 APR 2022 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23**

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

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[Patient Cloud Close Date & Time](#)

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18 APR 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23**

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

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[Patient Cloud Close Date & Time](#)

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25 APR 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23**

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

28 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

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

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	26 MAY 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 MAY 2022 23:59



US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

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

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[Patient Cloud Close Date & Time](#)

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06 JUN 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23**

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

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[Patient Cloud Open Date & Time](#)

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09 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUN 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23**

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

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 JUL 2022 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

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

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23**

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

21 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23**

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

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

**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: 26 Nov 2020 09:24:23**

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

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 09:24:23**

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

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

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

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[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23**

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

22 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

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

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[Patient Cloud Open Date & Time](#)

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29 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 OCT 2022 23:59

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US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

**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 ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

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

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

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

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3422281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:23

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 <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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

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 <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: 26 Nov 2020 09:24:23**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 09:24:23

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

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

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

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[Patient Cloud Close Date & Time](#)

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21 NOV 2022 23:59

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**US3422281**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:24:23**

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 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:24:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3422281

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3422281

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:24:23

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)

Generated On: 26 Nov 2020 09:24:23

AEID	USA-US082-2020-MRNA-1273-P30 1000003
Adverse event	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"/>
Number of Days in ICU	

v6.020 DTW (1102)

335 of 1712



US3422281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:23

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

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:24:23

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

Yes ☒

No ☐

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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)

Generated On: 26 Nov 2020 09:24:23

Name of Medication	OMEPRAZOLE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ACID REFLUX
Dose per administration	40
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:23

	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)

Generated On: 26 Nov 2020 09:24:23

Name of Medication	MELOXICAM
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	OSTEO-ARTHRITIS, GENERALIZED
Dose per administration	7.5
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:23

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

Generated On: 26 Nov 2020 09:24:23

Name of Medication	DILAUDID
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	PAIN POST PROCEDURE
Dose per administration	4
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:23

	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)

Generated On: 26 Nov 2020 09:24:23

Name of Medication	XARELTO
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	BLOOD CLOT PREVENTION
Dose per administration	10
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:23

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		27 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)		<input type="text"/>
Interval Dosage Unit Number (derived)		<input type="text"/>
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 (6)

Generated On: 26 Nov 2020 09:24:23

Name of Medication	BIOTIN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	HEALTH MAINTENANCE
Dose per administration	1000
Dose unit	mg <input type="checkbox"/> ug <input checked="" type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:23

	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)

Generated On: 26 Nov 2020 09:24:23

Name of Medication	CALCIUM CARBONATE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	GERD
Dose per administration	1000
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:23

	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)

Generated On: 26 Nov 2020 09:24:23

Name of Medication	MAGNESIUM CITRATE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	LAXATIVE
Dose per administration	296
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:23

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		05 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
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"/>
<hr/>		
Separate Dosage Number (derived)		<input type="text"/>
Interval Dosage Unit Number (derived)		<input type="text"/>
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)

Generated On: 26 Nov 2020 09:24:23

Name of Medication	SUPER C COMPLEX
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	HEALTH MAINTENANCE
Dose per administration	400
Dose unit	mg <input type="checkbox"/> ug <input checked="" type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:23

	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 Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:24:23

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3422281

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23

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: 26 Nov 2020 09:24:23

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

Generated On: 26 Nov 2020 09:24:23

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)	4

US3422281

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

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:24:23

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)	4
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)

Generated On: 26 Nov 2020 09:24:23

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)	4
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)

Generated On: 26 Nov 2020 09:24:23

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)	4
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)

Generated On: 26 Nov 2020 09:24:23

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)	4
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

Audit

US3422281 (Prod: Vanderbilt University Medical Center)

**US3422281**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 09:24:23**

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3422281'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	15 Sep 2020 15:34:35

US3422281

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:24:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:27:32

US3422281

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
User entered '15 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	15 Sep 2020 15:34:36

US3422281

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:24:23

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:27:32



**US3422281**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:24:23**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	15 Sep 2020 17:27:32

US3422281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:23

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1955'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	15 Sep 2020 15:34:37

US3422281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:23

[Age](#)

Audit	User	Time (GMT)
User entered '65'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:27:50

**US3422281**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:24:23**

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	15 Sep 2020 17:27:50

**US3422281**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:24:23**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '65'	System	15 Sep 2020 16:08:40

US3422281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:23

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:27:50

US3422281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:23

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:27:50

US3422281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:23

White

Audit	User	Time (GMT)
User entered 'I'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:27:50



US3422281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:23

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:27:50

US3422281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:23

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:27:50

US3422281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:23

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:27:50

US3422281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:23

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:27:50

US3422281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:23

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:27:50

US3422281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:23

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:27:50

US3422281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:23

Unknown

Audit	User	Time (GMT)
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:27:50

US3422281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:23

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:27:50



US3422281

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:23

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 16:08:40

**US3422281**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	15 Sep 2020 16:08:40

**US3422281**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
User entered '2020'	System	15 Sep 2020 16:08:40

US3422281

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:23

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	15 Sep 2020 16:08:40

US3422281

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 16:08:40

US3422281

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:23

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 16:08:40

US3422281

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:23

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 16:08:40

US3422281

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:23

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(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: 26 Nov 2020 09:24:23

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User closed query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	15 Sep 2020 16:08:45
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) <div></div>	15 Sep 2020 15:34:36

US3422281

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:24:23**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 16:08:40

US3422281

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:24:23

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 16:08:17

US3422281

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:24:23

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:28:05

US3422281

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:23

Condition

Audit	User	Time (GMT)
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) (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)	29 Oct 2020 19:59:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(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).	Coder Import (b) (4)	29 Oct 2020 19:59:23
Data point term sent to Coder	(b) (4)	28 Oct 2020 19:47:23
Coding entries removed.	April Hanlotxomphou (b) (4)	28 Oct 2020 19:47:17
User entered 'OSTEOARTHRTIS, GENERALIZED' reason for change: Data Entry Error	System	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).	April Hanlotxomphou (b) (4)	28 Oct 2020 19:47:13
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.	(b) (4), (b) (6)	27 Oct 2020 18:34:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	15 Sep 2020 17:29:54
Data point term sent to Coder	Coder Import (b) (4)	15 Sep 2020 17:29:54
	System	15 Sep 2020 17:28:46

**US3422281**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:24:23**

[Condition](#)

Audit	User	Time (GMT)
User entered 'Arthritis'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:28:21

**US3422281**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
User entered 'un UNK 2000' reason for change: New Information	(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

US3422281

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:28:21



US3422281

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:28:21

US3422281

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:28:21

US3422281

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:28:21

**US3422281**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
User entered '2000'	System	15 Sep 2020 17:28:21

**US3422281**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 17:28:21

**US3422281**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 17:28:21

US3422281

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:24:23

Condition

Audit	User	Time (GMT)
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) (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



US3422281

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:28:49

**US3422281**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:24:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:28:49

**US3422281**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:24:23**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Cindy Trimmer (b) (4)	15 Sep 2020 17:29:05
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	15 Sep 2020 17:28:49

**US3422281**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:28:49

**US3422281**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
User entered 'May 2020'	System	15 Sep 2020 17:28:49

**US3422281**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
User entered '2020'	System	15 Sep 2020 17:28:49

**US3422281**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (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)	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)	15 Sep 2020 17:29:20
	(b) (4)	

**US3422281**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
User entered 'un UNK 2008' reason for change: New Information	(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: 26 Nov 2020 09:24:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:29:20

US3422281

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:24:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:29:20

US3422281

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:29:20

US3422281

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:24:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:29:20

**US3422281**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
User entered '2008'	System	15 Sep 2020 17:29:20

**US3422281**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 17:29:20

**US3422281**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 17:29:20

US3422281

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:24:23

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4) (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) (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) (b) (4), (b) (6)	28 Oct 2020 19:57:42

US3422281

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	(b) (4), (b) (6)	28 Oct 2020 19:57:42

US3422281

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:24:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 19:57:42

US3422281

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:24:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 19:57:42

US3422281

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 19:57:42



US3422281

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:24:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 19:57:42

**US3422281**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	28 Oct 2020 19:57:42

**US3422281**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
User entered '2000'	System	28 Oct 2020 19:57:42

**US3422281**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 19:57:42

**US3422281**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 19:57:42

US3422281

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:24:23

Condition

Audit	User	Time (GMT)
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.	Coder Import (b) (4) (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) (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: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
User entered 'un UNK 2012'	(b) (4), (b) (6)	23 Nov 2020 16:05:35

US3422281

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:24:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Nov 2020 16:05:35



US3422281

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:24:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 16:05:35

US3422281

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
User entered 'un UNK 2012'	(b) (4), (b) (6)	23 Nov 2020 16:05:35

US3422281

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:24:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Nov 2020 16:05:35

**US3422281**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	23 Nov 2020 16:05:35

**US3422281**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
User entered '2012'	System	23 Nov 2020 16:05:35

**US3422281**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	23 Nov 2020 16:05:35

**US3422281**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
User entered '2012'	System	23 Nov 2020 16:05:35

US3422281

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:24:23

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolus - version MedDRA\\23.0.	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: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
User entered 'un UNK 2012'	(b) (4), (b) (6)	23 Nov 2020 16:06:27

US3422281

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:24:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Nov 2020 16:06:27

US3422281

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:24:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 16:06:27

US3422281

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
User entered 'un UNK 2012'	(b) (4), (b) (6)	23 Nov 2020 16:06:27

US3422281

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:24:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Nov 2020 16:06:27

**US3422281**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	23 Nov 2020 16:06:27

**US3422281**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
User entered '2012'	System	23 Nov 2020 16:06:27

**US3422281**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	23 Nov 2020 16:06:27



**US3422281**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
User entered '2012'	System	23 Nov 2020 16:06:27

US3422281

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:29:57

US3422281

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:29:57

US3422281

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
User entered '10:27'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:29:57

**US3422281**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:24:23**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 10:27'	System	15 Sep 2020 17:29:57

US3422281

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:23

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '65' in	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: 26 Nov 2020 09:24:23

[Weight \(.xxx.x\)](#)

Audit	User	Time (GMT)
User entered '150' lb	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: 26 Nov 2020 09:24:23**

**BMI (xxx.x)**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[BMI units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(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)	25 Sep 2020 18:29:04
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Cindy Trimmer (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)	21 Sep 2020 19:54:05
User entered '98.5' F	(b) (4)	
	Cindy Trimmer (b) (4)	15 Sep 2020 17:29:57
	(b) (4)	

US3422281

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:23

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4)	21 Sep 2020 19:54:05
User entered 'Oral (Oral)'	Cindy Trimmer (b) (4)	15 Sep 2020 17:29:57

US3422281

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:23

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:29:57

US3422281

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(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)	25 Sep 2020 18:29:04
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Cindy Trimmer (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)	21 Sep 2020 19:54:05
User entered '78'	Cindy Trimmer (b) (4)	15 Sep 2020 17:29:57

**US3422281**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:24:23**

[Pulse units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(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)	25 Sep 2020 18:29:04
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Cindy Trimmer (b) (4)	21 Sep 2020 19:54:18
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
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)	21 Sep 2020 19:54:05
User entered '14'	(b) (4)	
	Cindy Trimmer (b) (4)	15 Sep 2020 17:29:57
	(b) (4)	

**US3422281**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:24:23**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(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)	25 Sep 2020 18:29:04
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Cindy Trimmer (b) (4)	21 Sep 2020 19:54:21
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
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)	21 Sep 2020 19:54:05
User entered '149'	(b) (4)	
	Cindy Trimmer (b) (4)	15 Sep 2020 17:29:57
	(b) (4)	

**US3422281**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:24:23**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(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)	25 Sep 2020 18:29:04
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Cindy Trimmer (b) (4)	21 Sep 2020 19:54:24
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
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)	21 Sep 2020 19:54:05
User entered '72'	(b) (4)	
	Cindy Trimmer (b) (4)	15 Sep 2020 17:29:57
	(b) (4)	

**US3422281**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:24:23**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: Physical Examination

Generated On: 26 Nov 2020 09:24:23

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:30:14

US3422281

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:30:14

US3422281

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:24:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:56:47

US3422281

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:24:23

Is the participant of childbearing potential?

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:56:47



US3422281

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:24:23

If No, what is the reason?

Audit	User	Time (GMT)
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) (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)	15 Sep 2020 17:56:47

US3422281

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:24:23

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:56:47

US3422281

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:56:47

US3422281

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:24:23

Date of surgery unknown

Audit	User	Time (GMT)
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:56:47

US3422281

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:24:23

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered 'un UNK 2000' reason for change: New Information	(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: 26 Nov 2020 09:24:23

Date of last menstruation unknown

Audit	User	Time (GMT)
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:56:47

US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:23

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:23

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:59:43



US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:23

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:23

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:23

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:23

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:23

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:23

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:23

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:23

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:59:43



US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:23

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:23

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:23

[Specify](#)

Audit	User	Time (GMT)
User entered 'frequently in crowded public areas multiple times per week'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:23

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:23

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:23

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:23

**Resides in high density housing** (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:23

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:59:43



US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:23

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
User entered '1'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:23

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:23

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:59:43

US3422281

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:24:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:32:27

US3422281

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:24:23

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:32:27

US3422281

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:24:23

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:32:27

**US3422281**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:24:23**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	15 Sep 2020 17:32:27

US3422281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:23

What was the date of randomization? (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	15 Sep 2020 15:39:49



US3422281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:23

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '190955'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	15 Sep 2020 15:39:49

US3422281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:23

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	15 Sep 2020 15:39:49

US3422281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:23

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 16:09:03

US3422281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:23

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 16:09:03

US3422281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:23

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 16:09:03

US3422281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:23

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 16:09:03

US3422281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:23

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 16:09:03

US3422281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:23

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Trimmer (b) (4)	21 Sep 2020 19:54:30
Amendment Manager: DataPoint set to visible.	(b) (4)	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: 26 Nov 2020 09:24:23

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (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	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:24:23

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (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	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:24:23

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (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	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:24:23

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (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	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:23

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:24:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	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: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
User entered '10:27'	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: 26 Nov 2020 09:24:23

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.5' F	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: 26 Nov 2020 09:24:23

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 09:24:23

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:24:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '78'	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: 26 Nov 2020 09:24:23**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '14'	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: 26 Nov 2020 09:24:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Sep 2020 18:01:19



US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '149'	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: 26 Nov 2020 09:24:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '72'	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: 26 Nov 2020 09:24:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:24:23

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (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	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:24:23

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (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	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:23

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:24:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	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: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
User entered '11:36'	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: 26 Nov 2020 09:24:23

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.2' F	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: 26 Nov 2020 09:24:23

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 09:24:23

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:24:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '63'	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: 26 Nov 2020 09:24:23**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Sep 2020 18:01:19



US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '14'	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: 26 Nov 2020 09:24:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '140'	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: 26 Nov 2020 09:24:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '66'	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: 26 Nov 2020 09:24:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Sep 2020 18:01:19

US3422281

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:23

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:32:34

US3422281

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 17:32:34



US3422281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 16:09:26

US3422281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:23

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 16:09:26

US3422281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 16:09:26

US3422281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:23

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	15 Sep 2020 16:09:26

US3422281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 16:09:26

US3422281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:23

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:06'	(b) (4), (b) (6)	15 Sep 2020 16:09:26

**US3422281**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:24:23**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:06'	System	15 Sep 2020 16:09:26

US3422281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:23

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	15 Sep 2020 16:09:26



US3422281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:23

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	15 Sep 2020 16:09:26

US3422281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	15 Sep 2020 16:09:26

US3422281

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:01:37

US3422281

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:01:37

US3422281

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:33'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:01:37

**US3422281**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:24:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	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: 26 Nov 2020 09:24:23

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:24:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '10:38'	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: 26 Nov 2020 09:24:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cindy Trimmer (b) (4)	15 Sep 2020 18:01:48

US3422281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:24:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:24:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:24:23

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 18:01:48

US3422281

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:24:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:01:54



**US3422281**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:24:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 18:01:54

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	15 Sep 2020 16:39:27
User entered 'Yes (Y)'	System	15 Sep 2020 16:39:27

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	15 Sep 2020 16:39:27
User entered 'No (N)'	System	15 Sep 2020 16:39:27

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	15 Sep 2020 16:39:27
User entered '15 Sep 2020 11:39'	System	15 Sep 2020 16:39:27

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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-cb7afb3a42c'	System	16 Sep 2020 01:50:39
User entered 'Yes (Y)'	System	16 Sep 2020 01:50:39

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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-cb7afb3a42c'	System	16 Sep 2020 01:50:39
User entered '97.0'	System	16 Sep 2020 01:50:39

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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-cb7afb3a42c'	System	16 Sep 2020 01:50:39
User entered 'No (N)'	System	16 Sep 2020 01:50:39

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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-cb7afb3a42c'	System	16 Sep 2020 01:50:39
User entered '15 Sep 2020 20:50'	System	16 Sep 2020 01:50:39

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	17 Sep 2020 02:22:53
User entered 'Yes (Y)'	System	17 Sep 2020 02:22:53

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	17 Sep 2020 02:22:53
User entered 'No (N)'	System	17 Sep 2020 02:22:53

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	17 Sep 2020 02:22:53
User entered '16 Sep 2020 21:22'	System	17 Sep 2020 02:22:53

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	18 Sep 2020 10:59:51
User entered 'Yes (Y)'	System	18 Sep 2020 10:59:51



US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	18 Sep 2020 10:59:51
User entered '97.8'	System	18 Sep 2020 10:59:51

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	18 Sep 2020 10:59:51
User entered '18 Sep 2020 05:59'	System	18 Sep 2020 10:59:51

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	19 Sep 2020 11:54:56
User entered 'Yes (Y)'	System	19 Sep 2020 11:54:56

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	19 Sep 2020 11:54:56
User entered '97.5'	System	19 Sep 2020 11:54:56



US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	19 Sep 2020 11:54:56
User entered 'No (N)'	System	19 Sep 2020 11:54:56

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	19 Sep 2020 11:54:56
User entered '19 Sep 2020 06:54'	System	19 Sep 2020 11:54:56

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	20 Sep 2020 12:05:39
User entered '98.5'	System	20 Sep 2020 12:05:39

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	21 Sep 2020 13:45:37
User entered 'No (N)'	System	21 Sep 2020 13:45:37

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	22 Sep 2020 13:44:26
User entered 'Yes (Y)'	System	22 Sep 2020 13:44:26

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	22 Sep 2020 13:44:26
User entered '98.2'	System	22 Sep 2020 13:44:26

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	22 Sep 2020 13:44:26
User entered 'No (N)'	System	22 Sep 2020 13:44:26

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	22 Sep 2020 13:44:26
User entered '22 Sep 2020 08:44'	System	22 Sep 2020 13:44:26

US3422281

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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'	System	15 Sep 2020 16:41:30
User entered 'None (1)'	System	15 Sep 2020 16:41:30

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:24:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	15 Sep 2020 16:41:30
User entered 'No (N)'	System	15 Sep 2020 16:41:30

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	15 Sep 2020 16:41:30
User entered 'No (N)'	System	15 Sep 2020 16:41:30

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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'	System	15 Sep 2020 16:41:30
User entered 'None (1)'	System	15 Sep 2020 16:41:30

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	15 Sep 2020 16:41:30
User entered '15 Sep 2020 11:41'	System	15 Sep 2020 16:41:30

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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'	System	16 Sep 2020 01:51:10
User entered 'None (1)'	System	16 Sep 2020 01:51:10

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:24:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	16 Sep 2020 01:51:10
User entered 'No (N)'	System	16 Sep 2020 01:51:10

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	16 Sep 2020 01:51:10
User entered 'No (N)'	System	16 Sep 2020 01:51:10

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	17 Sep 2020 02:23:11
User entered 'No (N)'	System	17 Sep 2020 02:23:11

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	17 Sep 2020 02:23:11
User entered 'No (N)'	System	17 Sep 2020 02:23:11

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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'	System	18 Sep 2020 10:59:55
User entered 'None (1)'	System	18 Sep 2020 10:59:55

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:24:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	18 Sep 2020 10:59:55
User entered 'No (N)'	System	18 Sep 2020 10:59:55

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	18 Sep 2020 10:59:55
User entered 'No (N)'	System	18 Sep 2020 10:59:55

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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'	System	18 Sep 2020 10:59:55
User entered 'None (1)'	System	18 Sep 2020 10:59:55

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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'	System	19 Sep 2020 11:55:13
User entered 'None (1)'	System	19 Sep 2020 11:55:13

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:24:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	19 Sep 2020 11:55:13
User entered 'No (N)'	System	19 Sep 2020 11:55:13

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	19 Sep 2020 11:55:13
User entered 'No (N)'	System	19 Sep 2020 11:55:13

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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'	System	19 Sep 2020 11:55:13
User entered 'None (1)'	System	19 Sep 2020 11:55:13

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	19 Sep 2020 11:55:13
User entered '19 Sep 2020 06:55'	System	19 Sep 2020 11:55:13

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	20 Sep 2020 12:06:00
User entered 'No (N)'	System	20 Sep 2020 12:06:00

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	20 Sep 2020 12:06:00
User entered 'No (N)'	System	20 Sep 2020 12:06:00

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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'	System	21 Sep 2020 13:45:53
User entered 'None (1)'	System	21 Sep 2020 13:45:53

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:24:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	21 Sep 2020 13:45:53
User entered 'No (N)'	System	21 Sep 2020 13:45:53

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	21 Sep 2020 13:45:53
User entered 'No (N)'	System	21 Sep 2020 13:45:53

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	22 Sep 2020 13:44:47
User entered '22 Sep 2020 08:44'	System	22 Sep 2020 13:44:47

US3422281

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**HEADACHE**

Audit	User	Time (GMT)
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'	System	15 Sep 2020 16:42:30
User entered 'None (0)'	System	15 Sep 2020 16:42:30

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:24:23**

**FATIGUE**

Audit	User	Time (GMT)
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'	System	15 Sep 2020 16:42:30
User entered 'None (0)'	System	15 Sep 2020 16:42:30

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:24:23**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
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'	System	15 Sep 2020 16:42:30
User entered 'None (0)'	System	15 Sep 2020 16:42:30

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:24:23**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
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'	System	15 Sep 2020 16:42:30
User entered 'None (0)'	System	15 Sep 2020 16:42:30

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:24:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
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'	System	15 Sep 2020 16:42:30
User entered 'None (0)'	System	15 Sep 2020 16:42:30

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:24:23**

**CHILLS**

Audit	User	Time (GMT)
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'	System	15 Sep 2020 16:42:30
User entered 'None (0)'	System	15 Sep 2020 16:42:30



US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	15 Sep 2020 16:42:30
User entered 'No (N)'	System	15 Sep 2020 16:42:30

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	15 Sep 2020 16:42:30
User entered '15 Sep 2020 11:42'	System	15 Sep 2020 16:42:30

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**HEADACHE**

Audit	User	Time (GMT)
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'	System	16 Sep 2020 01:51:38
User entered 'None (0)'	System	16 Sep 2020 01:51:38

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:24:23**

**FATIGUE**

Audit	User	Time (GMT)
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'	System	16 Sep 2020 01:51:38
User entered 'None (0)'	System	16 Sep 2020 01:51:38

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:24:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
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'	System	16 Sep 2020 01:51:38
User entered 'None (0)'	System	16 Sep 2020 01:51:38



US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:24:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
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'	System	16 Sep 2020 01:51:38
User entered 'None (0)'	System	16 Sep 2020 01:51:38

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:24:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
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'	System	16 Sep 2020 01:51:38
User entered 'None (0)'	System	16 Sep 2020 01:51:38

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:24:23**

**CHILLS**

Audit	User	Time (GMT)
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'	System	16 Sep 2020 01:51:38
User entered 'None (0)'	System	16 Sep 2020 01:51:38

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	16 Sep 2020 01:51:38
User entered 'No (N)'	System	16 Sep 2020 01:51:38

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	16 Sep 2020 01:51:38
User entered '15 Sep 2020 20:51'	System	16 Sep 2020 01:51:38

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**HEADACHE**

Audit	User	Time (GMT)
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'	System	17 Sep 2020 02:23:31
User entered 'None (0)'	System	17 Sep 2020 02:23:31

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:24:23**

**FATIGUE**

Audit	User	Time (GMT)
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'	System	17 Sep 2020 02:23:31
User entered 'None (0)'	System	17 Sep 2020 02:23:31

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:24:23**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
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'	System	17 Sep 2020 02:23:31
User entered 'None (0)'	System	17 Sep 2020 02:23:31

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:24:23**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
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'	System	17 Sep 2020 02:23:31
User entered 'None (0)'	System	17 Sep 2020 02:23:31

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:24:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
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'	System	17 Sep 2020 02:23:31
User entered 'None (0)'	System	17 Sep 2020 02:23:31

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:24:23**

**CHILLS**

Audit	User	Time (GMT)
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'	System	17 Sep 2020 02:23:31
User entered 'None (0)'	System	17 Sep 2020 02:23:31

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
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



**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**HEADACHE**

Audit	User	Time (GMT)
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'	System	18 Sep 2020 11:00:21
User entered 'None (0)'	System	18 Sep 2020 11:00:21

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:24:23**

**FATIGUE**

Audit	User	Time (GMT)
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'	System	18 Sep 2020 11:00:21
User entered 'None (0)'	System	18 Sep 2020 11:00:21

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:24:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
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'	System	18 Sep 2020 11:00:21
User entered 'None (0)'	System	18 Sep 2020 11:00:21

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:24:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
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'	System	18 Sep 2020 11:00:21
User entered 'None (0)'	System	18 Sep 2020 11:00:21

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:24:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
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'	System	18 Sep 2020 11:00:21
User entered 'None (0)'	System	18 Sep 2020 11:00:21



**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:24:23**

**CHILLS**

Audit	User	Time (GMT)
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'	System	18 Sep 2020 11:00:21
User entered 'None (0)'	System	18 Sep 2020 11:00:21

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	18 Sep 2020 11:00:21
User entered 'No (N)'	System	18 Sep 2020 11:00:21

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**HEADACHE**

Audit	User	Time (GMT)
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'	System	19 Sep 2020 11:55:38
User entered 'None (0)'	System	19 Sep 2020 11:55:38

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:24:23**

**FATIGUE**

Audit	User	Time (GMT)
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'	System	19 Sep 2020 11:55:38
User entered 'None (0)'	System	19 Sep 2020 11:55:38



**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:24:23**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
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'	System	19 Sep 2020 11:55:38
User entered 'None (0)'	System	19 Sep 2020 11:55:38

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:24:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
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'	System	19 Sep 2020 11:55:38
User entered 'None (0)'	System	19 Sep 2020 11:55:38

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:24:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
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'	System	19 Sep 2020 11:55:38
User entered 'None (0)'	System	19 Sep 2020 11:55:38

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:24:23**

**CHILLS**

Audit	User	Time (GMT)
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'	System	19 Sep 2020 11:55:38
User entered 'None (0)'	System	19 Sep 2020 11:55:38

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	19 Sep 2020 11:55:38
User entered '19 Sep 2020 06:55'	System	19 Sep 2020 11:55:38

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**HEADACHE**

Audit	User	Time (GMT)
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'	System	20 Sep 2020 12:06:21
User entered 'None (0)'	System	20 Sep 2020 12:06:21

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:24:23**

**FATIGUE**

Audit	User	Time (GMT)
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'	System	20 Sep 2020 12:06:21
User entered 'None (0)'	System	20 Sep 2020 12:06:21

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:24:23**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
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'	System	20 Sep 2020 12:06:21
User entered 'None (0)'	System	20 Sep 2020 12:06:21

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:24:23**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**CHILLS**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	20 Sep 2020 12:06:21
User entered 'No (N)'	System	20 Sep 2020 12:06:21



**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**HEADACHE**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**FATIGUE**

Audit	User	Time (GMT)
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'	System	21 Sep 2020 13:46:21
User entered 'None (0)'	System	21 Sep 2020 13:46:21

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:24:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
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'	System	21 Sep 2020 13:46:21
User entered 'None (0)'	System	21 Sep 2020 13:46:21

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:24:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
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'	System	21 Sep 2020 13:46:21
User entered 'None (0)'	System	21 Sep 2020 13:46:21

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:24:23**

**CHILLS**

Audit	User	Time (GMT)
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'	System	21 Sep 2020 13:46:21
User entered 'None (0)'	System	21 Sep 2020 13:46:21

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	21 Sep 2020 13:46:21
User entered 'No (N)'	System	21 Sep 2020 13:46:21

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**HEADACHE**

Audit	User	Time (GMT)
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'	System	22 Sep 2020 13:45:08
User entered 'None (0)'	System	22 Sep 2020 13:45:08



**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:24:23**

**FATIGUE**

Audit	User	Time (GMT)
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'	System	22 Sep 2020 13:45:08
User entered 'None (0)'	System	22 Sep 2020 13:45:08

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:24:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
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'	System	22 Sep 2020 13:45:08
User entered 'None (0)'	System	22 Sep 2020 13:45:08

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:24:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
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'	System	22 Sep 2020 13:45:08
User entered 'None (0)'	System	22 Sep 2020 13:45:08

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:24:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
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'	System	22 Sep 2020 13:45:08
User entered 'None (0)'	System	22 Sep 2020 13:45:08

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:24:23**

**CHILLS**

Audit	User	Time (GMT)
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'	System	22 Sep 2020 13:45:08
User entered 'None (0)'	System	22 Sep 2020 13:45:08

US3422281

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	22 Sep 2020 13:45:08
User entered 'No (N)'	System	22 Sep 2020 13:45:08

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	22 Sep 2020 13:45:08
User entered '22 Sep 2020 08:45'	System	22 Sep 2020 13:45:08

**US3422281**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 22:16:17

US3422281

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Sep 2020 22:16:17

**US3422281**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:24:23**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 22:16:17

US3422281

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 22:16:23

**US3422281**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:24:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Sep 2020 22:16:23

US3422281

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 18:05:29



US3422281

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 18:05:29

US3422281

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Sep 2020 18:05:29

**US3422281**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:24:23**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 18:05:29

US3422281

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 18:05:38

**US3422281**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:24:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Sep 2020 18:05:38

US3422281

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Wendy Winn (b) (4) (b) (4)	06 Oct 2020 19:07:03

US3422281

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '6 Oct 2020'	Wendy Winn (b) (4) (b) (4)	06 Oct 2020 19:07:03

US3422281

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Wendy Winn (b) (4) (b) (4)	06 Oct 2020 19:07:03



**US3422281**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:24:23**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Wendy Winn (b) (4) (b) (4)	06 Oct 2020 19:07:03

US3422281

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Wendy Winn (b) (4) (b) (4)	06 Oct 2020 19:07:07

**US3422281**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:24:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Oct 2020 19:07:07

US3422281

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 16:28:49

US3422281

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 16:28:49

US3422281

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Oct 2020 16:28:49

**US3422281**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:24:23**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	14 Oct 2020 16:28:49

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:23

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
User entered '09:58'	(b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:23

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Temperature (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:23

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '075'	(b) (4), (b) (6)	14 Oct 2020 16:31:32



**US3422281**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:24:23**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '014'	(b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '139'	(b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '065'	(b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:23

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	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: 26 Nov 2020 09:24:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
User entered '11:08'	(b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:23

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.7' F	(b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:23

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:23

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '057'	(b) (4), (b) (6)	14 Oct 2020 16:31:32



**US3422281**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:24:23**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '012'	(b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '131'	(b) (4), (b) (6)	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Oct 2020 16:31:32

US3422281

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:23

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 16:32:59



US3422281

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 16:32:59

US3422281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
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) (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.' answered with 'correct' (Site from System).	Wendy Winn (b) (4)	14 Oct 2020 15:43:20
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)	14 Oct 2020 15:42:57

US3422281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:23

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Wendy Winn (b) (4) (b) (4)	14 Oct 2020 15:42:57

US3422281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
User entered empty.	Wendy Winn (b) (4) (b) (4)	14 Oct 2020 15:42:57

US3422281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:23

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	14 Oct 2020 15:42:57

US3422281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:23

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020' reason for change: Data Entry Error	Wendy Winn (b) (4)	14 Oct 2020 16:10:06
User entered empty.	Wendy Winn (b) (4)	14 Oct 2020 15:42:57

US3422281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:23

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:38'	Wendy Winn (b) (4) (b) (4)	14 Oct 2020 15:42:57

**US3422281**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:24:23**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Right Arm (RIGHT ARM)'	Wendy Winn (b) (4) (b) (4)	14 Oct 2020 15:42:57

US3422281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:23

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	14 Oct 2020 15:42:57

US3422281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	14 Oct 2020 15:42:57

US3422281

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 16:33:40

US3422281

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 16:33:40

US3422281

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:05'	(b) (4), (b) (6)	14 Oct 2020 16:33:40

US3422281

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:23

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	(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: 26 Nov 2020 09:24:23

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(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: 26 Nov 2020 09:24:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '10:03'	(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: 26 Nov 2020 09:24:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 09:24:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 09:24:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 16:34:23



US3422281

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 16:34:35

**US3422281**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:24:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Oct 2020 16:34:35

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	14 Oct 2020 16:11:11
User entered 'Yes (Y)'	System	14 Oct 2020 16:11:11

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	14 Oct 2020 16:11:11
User entered 'No (N)'	System	14 Oct 2020 16:11:11

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	14 Oct 2020 16:11:11
User entered '14 Oct 2020 11:11'	System	14 Oct 2020 16:11:11

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	14 Oct 2020 19:31:30
User entered 'Yes (Y)'	System	14 Oct 2020 19:31:30

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	14 Oct 2020 19:31:30
User entered 'No (N)'	System	14 Oct 2020 19:31:30

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	16 Oct 2020 10:59:43
User entered 'Yes (Y)'	System	16 Oct 2020 10:59:43

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	16 Oct 2020 10:59:43
User entered 'No (N)'	System	16 Oct 2020 10:59:43

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	17 Oct 2020 13:59:41
User entered 'Yes (Y)'	System	17 Oct 2020 13:59:41

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	17 Oct 2020 13:59:41
User entered 'No (N)'	System	17 Oct 2020 13:59:41

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	17 Oct 2020 13:59:41
User entered '17 Oct 2020 08:59'	System	17 Oct 2020 13:59:41

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	18 Oct 2020 12:46:13
User entered 'Yes (Y)'	System	18 Oct 2020 12:46:13



US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	18 Oct 2020 12:46:13
User entered '98.4'	System	18 Oct 2020 12:46:13

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	18 Oct 2020 12:46:13
User entered '18 Oct 2020 07:46'	System	18 Oct 2020 12:46:13

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	19 Oct 2020 15:08:23
User entered 'Yes (Y)'	System	19 Oct 2020 15:08:23

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	19 Oct 2020 15:08:23
User entered '98.2'	System	19 Oct 2020 15:08:23



US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	19 Oct 2020 15:08:23
User entered 'No (N)'	System	19 Oct 2020 15:08:23

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	19 Oct 2020 15:08:23
User entered '19 Oct 2020 09:58'	System	19 Oct 2020 15:08:23

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	20 Oct 2020 11:34:51
User entered 'Yes (Y)'	System	20 Oct 2020 11:34:51

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	20 Oct 2020 11:34:51
User entered '97.8'	System	20 Oct 2020 11:34:51

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	20 Oct 2020 11:34:51
User entered 'No (N)'	System	20 Oct 2020 11:34:51



**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	20 Oct 2020 11:34:51
User entered '20 Oct 2020 06:34'	System	20 Oct 2020 11:34:51

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
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

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3422281

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	14 Oct 2020 16:11:50
User entered 'No (N)'	System	14 Oct 2020 16:11:50

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	14 Oct 2020 16:11:50
User entered 'No (N)'	System	14 Oct 2020 16:11:50

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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'	System	14 Oct 2020 16:11:50
User entered 'None (1)'	System	14 Oct 2020 16:11:50

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	14 Oct 2020 16:11:50
User entered '14 Oct 2020 11:11'	System	14 Oct 2020 16:11:50



US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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'	System	14 Oct 2020 19:31:45
User entered 'None (1)'	System	14 Oct 2020 19:31:45

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:24:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	14 Oct 2020 19:31:45
User entered 'No (N)'	System	14 Oct 2020 19:31:45

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	14 Oct 2020 19:31:45
User entered 'No (N)'	System	14 Oct 2020 19:31:45

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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: '4dcb05f3-6f7e-4df5-a0b8-675c6e01ca4f'	System	14 Oct 2020 19:31:45
User entered 'None (1)'	System	14 Oct 2020 19:31:45

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: '4dcb05f3-6f7e-4df5-a0b8-675c6e01ca4f'	System	14 Oct 2020 19:31:45
User entered '14 Oct 2020 14:31'	System	14 Oct 2020 19:31:45



US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	16 Oct 2020 10:59:59
User entered '16 Oct 2020 05:59'	System	16 Oct 2020 10:59:59



US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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'	System	18 Oct 2020 12:46:39
User entered 'None (1)'	System	18 Oct 2020 12:46:39

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:24:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	18 Oct 2020 12:46:39
User entered 'No (N)'	System	18 Oct 2020 12:46:39

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	18 Oct 2020 12:46:39
User entered 'No (N)'	System	18 Oct 2020 12:46:39

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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'	System	18 Oct 2020 12:46:39
User entered 'None (1)'	System	18 Oct 2020 12:46:39

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	19 Oct 2020 15:08:27
User entered 'No (N)'	System	19 Oct 2020 15:08:27

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	19 Oct 2020 15:08:27
User entered 'No (N)'	System	19 Oct 2020 15:08:27

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	19 Oct 2020 15:08:27
User entered '19 Oct 2020 09:59'	System	19 Oct 2020 15:08:27



US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	21 Oct 2020 11:25:19
User entered 'No (N)'	System	21 Oct 2020 11:25:19

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	21 Oct 2020 11:25:19
User entered 'No (N)'	System	21 Oct 2020 11:25:19

US3422281

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:24:23**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**HEADACHE**

Audit	User	Time (GMT)
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'	System	14 Oct 2020 16:12:14
User entered 'None (0)'	System	14 Oct 2020 16:12:14

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:24:23**

**FATIGUE**

Audit	User	Time (GMT)
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'	System	14 Oct 2020 16:12:14
User entered 'None (0)'	System	14 Oct 2020 16:12:14

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:24:23**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
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'	System	14 Oct 2020 16:12:14
User entered 'None (0)'	System	14 Oct 2020 16:12:14

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:24:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
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'	System	14 Oct 2020 16:12:14
User entered 'None (0)'	System	14 Oct 2020 16:12:14

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:24:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
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'	System	14 Oct 2020 16:12:14
User entered 'None (0)'	System	14 Oct 2020 16:12:14



**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:24:23**

**CHILLS**

Audit	User	Time (GMT)
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'	System	14 Oct 2020 16:12:14
User entered 'None (0)'	System	14 Oct 2020 16:12:14

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	14 Oct 2020 16:12:14
User entered 'No (N)'	System	14 Oct 2020 16:12:14

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	14 Oct 2020 16:12:14
User entered '14 Oct 2020 11:12'	System	14 Oct 2020 16:12:14

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**HEADACHE**

Audit	User	Time (GMT)
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'	System	14 Oct 2020 19:32:08
User entered 'None (0)'	System	14 Oct 2020 19:32:08

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:24:23**

**FATIGUE**

Audit	User	Time (GMT)
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'	System	14 Oct 2020 19:32:08
User entered 'None (0)'	System	14 Oct 2020 19:32:08



US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:24:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
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'	System	14 Oct 2020 19:32:08
User entered 'None (0)'	System	14 Oct 2020 19:32:08

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:24:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
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'	System	14 Oct 2020 19:32:08
User entered 'None (0)'	System	14 Oct 2020 19:32:08

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:24:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
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'	System	14 Oct 2020 19:32:08
User entered 'None (0)'	System	14 Oct 2020 19:32:08

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:24:23**

**CHILLS**

Audit	User	Time (GMT)
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'	System	14 Oct 2020 19:32:08
User entered 'None (0)'	System	14 Oct 2020 19:32:08

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	14 Oct 2020 19:32:08
User entered '14 Oct 2020 14:32'	System	14 Oct 2020 19:32:08

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**HEADACHE**

Audit	User	Time (GMT)
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'	System	16 Oct 2020 11:00:19
User entered 'None (0)'	System	16 Oct 2020 11:00:19

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:24:23**

**FATIGUE**

Audit	User	Time (GMT)
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'	System	16 Oct 2020 11:00:19
User entered 'None (0)'	System	16 Oct 2020 11:00:19

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:24:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
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'	System	16 Oct 2020 11:00:19
User entered 'None (0)'	System	16 Oct 2020 11:00:19

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:24:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
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'	System	16 Oct 2020 11:00:19
User entered 'None (0)'	System	16 Oct 2020 11:00:19

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:24:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
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'	System	16 Oct 2020 11:00:19
User entered 'None (0)'	System	16 Oct 2020 11:00:19

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:24:23**

**CHILLS**

Audit	User	Time (GMT)
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'	System	16 Oct 2020 11:00:19
User entered 'None (0)'	System	16 Oct 2020 11:00:19

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	16 Oct 2020 11:00:19
User entered 'No (N)'	System	16 Oct 2020 11:00:19



**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	16 Oct 2020 11:00:19
User entered '16 Oct 2020 06:00'	System	16 Oct 2020 11:00:19

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**HEADACHE**

Audit	User	Time (GMT)
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

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:24:23**

**FATIGUE**

Audit	User	Time (GMT)
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

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:24:23**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
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



**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:24:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**CHILLS**

Audit	User	Time (GMT)
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

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**HEADACHE**

Audit	User	Time (GMT)
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'	System	18 Oct 2020 12:46:58
User entered 'None (0)'	System	18 Oct 2020 12:46:58



**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:24:23**

**FATIGUE**

Audit	User	Time (GMT)
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'	System	18 Oct 2020 12:46:58
User entered 'None (0)'	System	18 Oct 2020 12:46:58

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:24:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
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'	System	18 Oct 2020 12:46:58
User entered 'None (0)'	System	18 Oct 2020 12:46:58

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:24:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
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'	System	18 Oct 2020 12:46:58
User entered 'None (0)'	System	18 Oct 2020 12:46:58

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:24:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
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'	System	18 Oct 2020 12:46:58
User entered 'None (0)'	System	18 Oct 2020 12:46:58

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:24:23**

**CHILLS**

Audit	User	Time (GMT)
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'	System	18 Oct 2020 12:46:58
User entered 'None (0)'	System	18 Oct 2020 12:46:58

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	18 Oct 2020 12:46:58
User entered 'No (N)'	System	18 Oct 2020 12:46:58

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	18 Oct 2020 12:46:58
User entered '18 Oct 2020 07:46'	System	18 Oct 2020 12:46:58

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**HEADACHE**

Audit	User	Time (GMT)
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'	System	19 Oct 2020 15:08:29
User entered 'None (0)'	System	19 Oct 2020 15:08:29

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:24:23**

**FATIGUE**

Audit	User	Time (GMT)
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'	System	19 Oct 2020 15:08:29
User entered 'None (0)'	System	19 Oct 2020 15:08:29

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:24:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
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'	System	19 Oct 2020 15:08:29
User entered 'None (0)'	System	19 Oct 2020 15:08:29

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:24:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
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'	System	19 Oct 2020 15:08:29
User entered 'None (0)'	System	19 Oct 2020 15:08:29

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:24:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
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'	System	19 Oct 2020 15:08:29
User entered 'None (0)'	System	19 Oct 2020 15:08:29

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:24:23**

**CHILLS**

Audit	User	Time (GMT)
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'	System	19 Oct 2020 15:08:29
User entered 'None (0)'	System	19 Oct 2020 15:08:29



US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	19 Oct 2020 15:08:29
User entered '19 Oct 2020 09:59'	System	19 Oct 2020 15:08:29

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**HEADACHE**

Audit	User	Time (GMT)
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'	System	20 Oct 2020 11:35:29
User entered 'None (0)'	System	20 Oct 2020 11:35:29

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:24:23**

**FATIGUE**

Audit	User	Time (GMT)
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'	System	20 Oct 2020 11:35:29
User entered 'None (0)'	System	20 Oct 2020 11:35:29

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:24:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
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'	System	20 Oct 2020 11:35:29
User entered 'None (0)'	System	20 Oct 2020 11:35:29



US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:24:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
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'	System	20 Oct 2020 11:35:29
User entered 'None (0)'	System	20 Oct 2020 11:35:29

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:24:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
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'	System	20 Oct 2020 11:35:29
User entered 'None (0)'	System	20 Oct 2020 11:35:29

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:24:23**

**CHILLS**

Audit	User	Time (GMT)
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'	System	20 Oct 2020 11:35:29
User entered 'None (0)'	System	20 Oct 2020 11:35:29

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	20 Oct 2020 11:35:29
User entered 'No (N)'	System	20 Oct 2020 11:35:29

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**HEADACHE**

Audit	User	Time (GMT)
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'	System	21 Oct 2020 11:25:37
User entered 'None (0)'	System	21 Oct 2020 11:25:37

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:24:23**

**FATIGUE**

Audit	User	Time (GMT)
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'	System	21 Oct 2020 11:25:37
User entered 'None (0)'	System	21 Oct 2020 11:25:37

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:24:23

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
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'	System	21 Oct 2020 11:25:37
User entered 'None (0)'	System	21 Oct 2020 11:25:37

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:24:23

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
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'	System	21 Oct 2020 11:25:37
User entered 'None (0)'	System	21 Oct 2020 11:25:37

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:24:23**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
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'	System	21 Oct 2020 11:25:37
User entered 'None (0)'	System	21 Oct 2020 11:25:37

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:24:23**

**CHILLS**

Audit	User	Time (GMT)
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'	System	21 Oct 2020 11:25:37
User entered 'None (0)'	System	21 Oct 2020 11:25:37

US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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'	System	21 Oct 2020 11:25:37
User entered 'No (N)'	System	21 Oct 2020 11:25:37

**US3422281**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:24:23**

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	21 Oct 2020 11:25:37
User entered '21 Oct 2020 06:25'	System	21 Oct 2020 11:25:37



US3422281

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	22 Oct 2020 14:09:49

US3422281

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Cindy Trimmer (b) (4) (b) (4)	22 Oct 2020 14:09:49

US3422281

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Cindy Trimmer (b) (4) (b) (4)	22 Oct 2020 14:09:49

US3422281

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:23

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	22 Oct 2020 14:09:49

US3422281

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	22 Oct 2020 14:09:57

**US3422281**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:24:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Oct 2020 14:09:57



US3422281

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 21:17:14

US3422281

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Oct 2020 21:17:14

**US3422281**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:24:23**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:17:14

US3422281

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 21:17:20

**US3422281**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:24:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Oct 2020 21:17:20

US3422281

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:21:42

US3422281

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '4 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 19:21:42



US3422281

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Nov 2020 19:21:42

**US3422281**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:24:23**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:21:42

US3422281

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:21:30

**US3422281**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:24:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Nov 2020 19:21:30

US3422281

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	24 Nov 2020 19:13:02

US3422281

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:23

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Cindy Trimmer (b) (4) (b) (4)	24 Nov 2020 19:13:02

**US3422281**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:24:23**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	24 Nov 2020 19:13:02



US3422281

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:23

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	24 Nov 2020 19:13:42

US3422281

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	24 Nov 2020 19:13:42

US3422281

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	24 Nov 2020 19:13:55

US3422281

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Nov 2020'	Cindy Trimmer (b) (4) (b) (4)	24 Nov 2020 19:13:55

US3422281

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '09:00'	Cindy Trimmer (b) (4) (b) (4)	24 Nov 2020 19:13:55

**US3422281**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:24:23**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	24 Nov 2020 19:13:58

**US3422281**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:24:23**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Nov 2020 19:13:58



**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[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: '2020-11-15T08:30:46', 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: 26 Nov 2020 09:24:23**

Have you been exposed to someone with 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: '2020-11-15T08:30:51', 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: 26 Nov 2020 09:24:23**

[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: '2020-11-15T08:30:59', 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: 26 Nov 2020 09:24:23**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:38:09
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 08:38:09

**US3422281**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:24:23**

[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 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: 26 Nov 2020 09:24:23**

[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 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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

**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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:24:23

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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 'USA-US082-2020-mRNA-1273-P301000003'	System	02 Nov 2020 20:42:12
User entered 'New'	(b) (4), (b) (6)	02 Nov 2020 20:42:12

US3422281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:23

[Adverse event](#)

Audit	User	Time (GMT)
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
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

US3422281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:23

[Adverse event](#)

Audit	User	Time (GMT)
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
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



**US3422281**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 09:24:23**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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

**US3422281**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

**If not Ongoing, end date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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

**US3422281**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 09:24:23**

[AE End 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: 26 Nov 2020 09:24:23

Severity

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3422281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:23

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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

**US3422281**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 09:24:23**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
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

**US3422281**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 09:24:23**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

**US3422281**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 09:24:23**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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



**US3422281**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 09:24:23**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

**US3422281**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 09:24:23**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

[Concomitant Medication](#)

Audit	User	Time (GMT)
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

US3422281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:23

[Concomitant Procedure](#)

Audit	User	Time (GMT)
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

**US3422281**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 09:24:23**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

**US3422281**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 09:24:23**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
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

US3422281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:23

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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
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

US3422281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:23

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (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: 26 Nov 2020 09:24:23**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Oct 2020 20:33:47

**US3422281**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 09:24:23**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Oct 2020 20:33:47

**US3422281**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:58:22
User entered 'acid reflux'	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: 26 Nov 2020 09:24:23**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:58:24
User entered '40'	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: 26 Nov 2020 09:24:23

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:58:28
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: 26 Nov 2020 09:24:23**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:58:29
User entered 'once daily (QD)'	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: 26 Nov 2020 09:24:23**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
DataPoint Verified.	(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) (b) (4)	15 Sep 2020 18:02:46

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:24:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:58:42
User entered '0'	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: 26 Nov 2020 09:24:23**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(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) (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) (b) (4)	06 Nov 2020 10:53:33
Data point term sent to Coder Coding entries removed.	System April Hanlotxomphou (b) (4)	28 Oct 2020 19:44:13 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) (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) (b) (4)	15 Sep 2020 18:04:50
Data point term sent to Coder User entered 'Meloxicam'	System Cindy Trimmer (b) (4) (b) (4)	15 Sep 2020 18:03:53 15 Sep 2020 18:03:27

US3422281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:23

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'No (N)'	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: 26 Nov 2020 09:24:23

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	15 Sep 2020 18:03:27

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:24:23**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered '7.5'	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: 26 Nov 2020 09:24:23**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered empty.	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: 26 Nov 2020 09:24:23

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'once daily (QD)'	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: 26 Nov 2020 09:24:23**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered empty.	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: 26 Nov 2020 09:24:23**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:24:23**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered empty.	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: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
DataPoint Verified.	(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) (b) (4)	15 Sep 2020 18:03:27

US3422281

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:24:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered '0'	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: 26 Nov 2020 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'Yes (Y)'	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: 26 Nov 2020 09:24:23**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered empty.	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: 26 Nov 2020 09:24:23**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:15:37
User entered 'No (N)'	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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per ETRTR: Please confirm start date for this and related Medications to SAE "Osteoarthritis" (Procedure dated 27Oct20), thanks.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	15 Nov 2020 21:01:56
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: 26 Nov 2020 09:24:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	13 Nov 2020 21:51:27
DataPoint Un-verified.	Naomi Kown (b) (4)	13 Nov 2020 21:51:18
User entered 'No (N)' reason for change: Data Entry Error	Naomi Kown (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: 26 Nov 2020 09:24:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	13 Nov 2020 21:51:18
DataPoint Verified.	Naomi Kown (b) (4)	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: 26 Nov 2020 09:24:23**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (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.	Coder Import (b) (4) (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: 26 Nov 2020 09:24:23

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
Query 'Please confirm this medication is still ongoing. ' answered with 'yes, it is still ongoing' (Site from CRA).	Naomi Kown (b) (4)	24 Nov 2020 19:24:18
User opened query 'Please confirm this medication is still ongoing. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 20:00:27
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:31:17
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: 26 Nov 2020 09:24:23**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	05 Nov 2020 21:17:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(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: 26 Nov 2020 09:24:23

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

[Indication](#)

Audit	User	Time (GMT)
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). User entered 'laxative'	(b) (4), (b) (6)	19 Nov 2020 20:09:25
	(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: 26 Nov 2020 09:24:23**

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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 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: 26 Nov 2020 09:24:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[Name of Medication](#)

Audit	User	Time (GMT)
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)	23 Nov 2020 08:25:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 20:15:37
Data point term sent to Coder	System	05 Nov 2020 21:24:51
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: 26 Nov 2020 09:24:23

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[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: 26 Nov 2020 09:24:23**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 21:21:30

US3422281

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 09:24:23**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	(b) (4), (b) (6)	18 Nov 2020 21:37:11
User entered 'PRIMARY LEFT TOTAL KNEE ARTHROPLASTY' reason for change: New Information	(b) (4), (b) (6)	18 Nov 2020 21:37:11
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:32:15
User opened query 'Please ensure to split term out, ie, "Primary Left Total Knee Arthroplasty". ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 21:31:56
User entered 'primaryLEFT total KNEE arthroplasty' reason for change: New Information	(b) (4), (b) (6)	30 Oct 2020 20:27:34
User entered 'left knee replacement'	(b) (4), (b) (6)	29 Oct 2020 21:16:05

US3422281

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:24:23

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Investigator Country](#)

Audit	User	Time (GMT)
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 'US'	System	02 Nov 2020 20:43:14



**US3422281**

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

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:24:23**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Investigator Country](#)

Audit	User	Time (GMT)
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 'US'	System	02 Nov 2020 20:43:14



**US3422281**

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

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:24:23**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
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)	02 Nov 2020 20:43:14

**US3422281**

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

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:24:23**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Investigator Country](#)

Audit	User	Time (GMT)
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 'US'	System	02 Nov 2020 20:43:14

**US3422281**

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

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:24:23**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Investigator Country](#)

Audit	User	Time (GMT)
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 'US'	System	02 Nov 2020 20:43:14

**US3422281**

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

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:24:23**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:24:23**

[Investigator Country](#)

Audit	User	Time (GMT)
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 'US'	System	02 Nov 2020 20:43:14

**US3422281**

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

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:24:23**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:24:23**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '24/Nov/2020 16:08'	System	24 Nov 2020 21:08:10



US3422281

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

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:24:23

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 21:08:10