

US3362222 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:59:15

All time stamps listed in this document are displayed in GMT

**US3362222**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:59:15**

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[Participant ID](#)

US3362222

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

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US3362222

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:59:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:15

Date of Birth (MMM yyyy)	(b) (6) 1969
Age	51
Age Units	YEARS
Age (Derived)	51
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:15

Date of Informed Consent ( <i>dd MMM yyyy</i> )	22 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input 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 10:59:15

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:59:15

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:15

Condition	BILATERAL TUBAL LIGATION
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013



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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:15

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

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:15

Condition	MIGRAINE
Start date (dd MMM yyyy)	UN UNK 1984
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 1984
Start Year (derived)	1984
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:15

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

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:15

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

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:15

Condition	ANAL FISSURE REPAIR
Start date (dd MMM yyyy)	UN JUN 2019
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 JUN 2019
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JUN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:15

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 1984
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 1984
Start Year (derived)	1984
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:15

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1984
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 1984
Start Year (derived)	1984
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:59:15

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



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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	22 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	15:53 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 15:53
Height ( <i>xxx.x</i> )	162.6 cm
Weight ( <i>xxx.x</i> )	79.8 kg
BMI ( <i>xxx.x</i> )	30.18296 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 10:59:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 AUG 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 10:59:15

Date of assessment (*dd MMM yyyy*) 22 AUG 2020

Is the participant of childbearing potential? Yes ☒ No ☐

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

If Partner medically sterile or Other, specify \_\_\_\_\_

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:59:15

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	22 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:15

**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**

PART TIME REPORTER  
(b) (6) COMES  
INTO CONTACT WITH PEOPLE  
DAILY

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

**No Risk Identified** False

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

v6.020 DTW (1102)

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:15

<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)	True
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	False
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:59:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:15

What was the date of randomization? (dd MMM yyyy) 28 AUG 2020

What was the participant's randomization number? 145056

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

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

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

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

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

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

Liver Disease Yes ☐   
 No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐   
 No ☒



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:15

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 10:59:15

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)	28 AUG 2020
Time of assessment (00:00-23:59)	15:53 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 15:53
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

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)	28 AUG 2020
Time of assessment (00:00-23:59)	17:21 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 17:21
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 AUG 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: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:59:15

Was the pregnancy test performed? Yes ☐  
No ☒

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

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☐

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

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

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:15

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)	28 AUG 2020
What was the treatment time? (00:00-23:59)	16:11 (24 HR)
Treatment Date and Time (derived)	28 AUG 2020 16:11
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	28 AUG 2020
Collection time ( <i>00:00-23:59</i> )	16:07 (24 HR)
Collection date and time (derived)	28 AUG 2020 16:07

US3362222

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:59:15

Collection date ( <i>dd MMM yyyy</i> )			28 AUG 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:08	28 AUG 2020 16:08
Nasopharyngeal Swab 2	No		



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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:59:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

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**TIMEPOINT**

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

---

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.3 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

28 AUG 2020 17:17

---

PC Open Date & Time

28 AUG 2020 16:31

---

PC Close Date & Time

28 AUG 2020 19:01

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °F

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

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

PC Time Stamp	28 AUG 2020 22:36
PC Open Date & Time	28 AUG 2020 19:56
PC Close Date & Time	29 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:59:15

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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

98.6 °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

29 AUG 2020 21:15

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:15

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	99.0 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	30 AUG 2020 20:41
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:59:15

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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

97.1 °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

31 AUG 2020 23:27

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:59:15

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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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 02:39

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:59:15

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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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 01:59

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59



US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:59:15

---

**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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 23:46

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

**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

28 AUG 2020 17:18

PC Open Date & Time

28 AUG 2020 16:31

PC Close Date & Time

28 AUG 2020 19:01

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

**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

28 AUG 2020 22:37

PC Open Date & Time

28 AUG 2020 19:56

PC Close Date & Time

29 AUG 2020 11:59

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:59:15

**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

29 AUG 2020 21:11

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:15

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

6

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 20:42

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:59:15

**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

31 AUG 2020 23:25

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:59:15

**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

02 SEP 2020 02:37

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:59:15

**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

03 SEP 2020 02:00

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59



US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:59:15

**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

03 SEP 2020 23:45

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

**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 ☐

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 17:19
PC Open Date & Time	28 AUG 2020 16:31
PC Close Date & Time	28 AUG 2020 19:01

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

**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 ☐

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 22:38
PC Open Date & Time	28 AUG 2020 19:56
PC Close Date & Time	29 AUG 2020 11:59

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:59:15

**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 ☒

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:59:15

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 21:15
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:59:15

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 ☒



US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:59:15

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 20:43
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:59:15

**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 ☒

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:59:15

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 23:25
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:59:15

**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 ☒

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:59:15

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 02:38
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:59:15

**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 ☒

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:59:15

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 02:00
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:59:15

**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 ☒



US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:59:15

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 23:46
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3362222

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

04 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362222

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362222

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362222

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362222

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362222

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362222

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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



US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

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)	2 OCT 2020
Time of assessment (00:00-23:59)	08:15 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 08:15
Temperature (xxx.x)	37 C
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)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

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)	2 OCT 2020
Time of assessment (00:00-23:59)	10:05 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 10:05
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3362222

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 OCT 2020

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

US3362222

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:59:15

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	02 OCT 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3362222

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:15

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)	02 OCT 2020
What was the treatment time? (00:00-23:59)	09:29 (24 HR)
Treatment Date and Time (derived)	02 OCT 2020 09:29
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3362222

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	02 OCT 2020
Collection time ( <i>00:00-23:59</i> )	09:00 (24 HR)
Collection date and time (derived)	02 OCT 2020 09:00

US3362222

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:59:15

Collection date ( <i>dd MMM yyyy</i> )			02 OCT 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:03	02 OCT 2020 09:03
Nasopharyngeal Swab 2	No		

US3362222

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

**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

98.0 °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

02 OCT 2020 10:10

PC Open Date & Time

02 OCT 2020 09:49

PC Close Date & Time

02 OCT 2020 12:19

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

**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 98.7 °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):

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

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

PC Time Stamp 02 OCT 2020 21:14

PC Open Date & Time 02 OCT 2020 13:14

PC Close Date & Time 03 OCT 2020 11:59

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:59:15

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.1 °F
Was any <b>MEDICATION TAKEN today for pain or fever</b> ?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	03 OCT 2020 22:49
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:15

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.1 °F
Was any <b>MEDICATION TAKEN today for pain or fever</b> ?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	False
To <b>PREVENT</b> pain or fever from occurring	True
PC Time Stamp	04 OCT 2020 22:53
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:59:15

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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

98.6 °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

05 OCT 2020 22:55

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:59:15

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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

98.4 °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

06 OCT 2020 23:08

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:59:15

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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

97.5 °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

07 OCT 2020 22:30

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:59:15

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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

97.1 °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

08 OCT 2020 22:28

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59



US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

**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

02 OCT 2020 10:11

PC Open Date & Time

02 OCT 2020 09:49

PC Close Date & Time

02 OCT 2020 12:19

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

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

7

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 21:11

PC Open Date & Time

02 OCT 2020 13:14

PC Close Date & Time

03 OCT 2020 11:59

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:59:15

**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 ☐

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

2

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

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

Yes ☒

No ☐

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

2

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 22:50

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:15

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

3

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 22:51

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:59:15

**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

05 OCT 2020 22:55

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:59:15

**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

06 OCT 2020 22:40

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:59:15

**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

07 OCT 2020 22:28

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:59:15

**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

08 OCT 2020 18:57

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59



US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

**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 ☐

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 10:12
PC Open Date & Time	02 OCT 2020 09:49
PC Close Date & Time	02 OCT 2020 12:19

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

**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 ☐

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 21:15
PC Open Date & Time	02 OCT 2020 13:14
PC Close Date & Time	03 OCT 2020 11:59

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:59:15

**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 ☒

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:59:15

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 22:51
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:59:15

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 ☒

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:59:15

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 22:51
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59



US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:59:15

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 ☒

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:59:15

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 22:55
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:59:15

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 ☒

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:59:15

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 22:41
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:59:15

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 ☒

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:59:15

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 22:28
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:59:15

**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 ☒

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:59:15

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 18:58
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59



US3362222

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362222

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362222

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362222

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362222

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362222

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362222

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3362222

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	2 NOV 2020
Time of assessment ( <i>00:00-23:59</i> )	07:36 (24 HR)
Vital Signs Date and Time (derived)	2 NOV 2020 07:36
Temperature ( <i>xxx.x</i> )	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	71 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3362222

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 NOV 2020

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

US3362222

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	2 NOV 2020
Collection time ( <i>00:00-23:59</i> )	08:00 (24 HR)
Collection date and time (derived)	2 NOV 2020 08:00

US3362222

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362222

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	01 NOV 2020 21:41:06
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

US3362222

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 NOV 2020 12:03:59

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3362222

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 NOV 2020 14:23:59

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 OCT 2020 23:59



US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 NOV 2020 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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="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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 19:43:38
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>



**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

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03 DEC 2020 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 DEC 2020 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 DEC 2020 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>



**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 DEC 2020 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

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07 JAN 2021 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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="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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JAN 2021 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>



**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 JAN 2021 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	31 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 FEB 2021 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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="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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

14 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>



**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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="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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Open Date & Time](#)

07 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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="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"/>



**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

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25 MAR 2021 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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="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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Open Date & Time](#)

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28 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 APR 2021 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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="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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 APR 2021 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>



**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

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22 APR 2021 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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="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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

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13 MAY 2021 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>



**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Open Date & Time](#)

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23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAY 2021 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

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03 JUN 2021 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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



**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 JUN 2021 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

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08 JUL 2021 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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



**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

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22 JUL 2021 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Open Date & Time](#)

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01 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 AUG 2021 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>



**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**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 ☐

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**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 ☐

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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 ☐



**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 SEP 2021 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

12 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**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 ☐

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>



**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

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07 OCT 2021 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**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 ☐

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

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21 OCT 2021 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**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 ☐

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 OCT 2021 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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



**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

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04 NOV 2021 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>



**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Open Date & Time](#)

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28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

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

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

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 DEC 2021 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**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 ☐

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 DEC 2021 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>



**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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 <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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**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 ☐

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**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 ☐

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

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17 FEB 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

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

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



**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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 ☐

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

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03 MAR 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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 ☐

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**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 ☐

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

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17 MAR 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**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 ☐



**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**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 ☐

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**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 ☐

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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



**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

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21 APR 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>



**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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 ☐

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

DAY 642

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

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02 JUN 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**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 ☐

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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 ☐



**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

12 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**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 ☐

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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 ☐

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 JUL 2022 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

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

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



**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUL 2022 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUL 2022 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**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 ☐

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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="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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Open Date & Time](#)

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31 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 AUG 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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="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"/>



**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2022 23:59
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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 AUG 2022 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>



**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

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08 SEP 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Open Date & Time](#)

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11 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 SEP 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

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

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

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22 SEP 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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"/>



**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**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 ☐

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

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[Patient Cloud Close Date & Time](#)

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13 OCT 2022 23:59

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US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 OCT 2022 23:59

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

US3362222

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

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



**US3362222**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 NOV 2022 23:59

**US3362222**

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

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:15**

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*

**US3362222**

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

**Form: Continuing**

**Generated On: 26 Nov 2020 10:59:15**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3362222

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:59:15

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"/>

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3362222

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:59:15

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3362222

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

AEID	USA-US112-2020-MRNA-1273-P30 1000005
Adverse event	CHOLECYSTITIS
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)	09 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)	11 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 type="radio"/> Grade 4 <input checked="" 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)	10 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	11 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)	342 of 2143

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

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	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PATIENT STARTED WITH RUQ ABDOMINAL PAIN ON 09OCT2020, WENT TO ER AND ADMITTED FOR TREATMENT/SURGICAL REMOVAL OF GALLBLADDER DUE TO CHOLECYSTITIS
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1

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**US3362222**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:15**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:59:15

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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.

---

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:15

Name of Medication	LEVOTHYROXIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPOTHYROIDISM
Dose per administration	75
Dose unit	mg <input type="radio"/> ug <input checked="" 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"/>

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:15

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 FEB 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"/>

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:15

Name of Medication	SUMATRIPTIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	MIGRAINE
Dose per administration	100
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 checked="" 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"/>

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:15

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

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:15

Name of Medication	TOPIRAMATE
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	MIGRAINE
Dose per administration	50
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"/>

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:15

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:15

Name of Medication	BUPROPRIONE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ANXIETY
Dose per administration	300
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"/>

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:15

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

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:15

Name of Medication	ALBUTEROL 0.5-2.5MG/ML
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ASTHMA
Dose per administration	2
Dose unit	mg <input 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 checked="" 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 checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:15

	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date ( <i>dd MMM yyyy</i> )	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date ( <i>dd MMM yyyy</i> ) <hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	<hr/>	
Interval Dosage Unit Number (derived)	<hr/>	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:15

Name of Medication	CYMBALTA
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	MEDICAL HISTORY MIGRAINE PROPHYLAXIS
Dose per administration	60
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"/>

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:15

	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)		08 SEP 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"/>

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:15

Name of Medication	TYLENOL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	HEADACHE, PAIN AT INJECTION SITE, MUSCLE ACHES, FATIGUE, TO TREAT/PREVENT PAIN/FEVER FROM OCCURRING/ALREADY OCCURRED.
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 checked="" 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:15

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		3 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)		4 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		4
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:15

Name of Medication	OXYCODONE
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	POST OPERATIVE PAIN/PREVENTION
Dose per administration	5
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 checked="" 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 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)		12 OCT 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:15

Name of Medication	COLACE
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	CONSTIPATION PREVENTION
Dose per administration	100
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 checked="" 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:15

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:15

Name of Medication	ROBAXIN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	CHOLELITHIASIS
Dose per administration	500
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"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:15

Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	11 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)	17 OCT 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/>
	803 <input type="checkbox"/>
	804 <input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:15

Name of Medication	GLYCOPYRROLATE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	CHOLECYSTECTOMY
Dose per administration	0.8
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 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 type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:15

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date ( <i>dd MMM yyyy</i> )		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date ( <i>dd MMM yyyy</i> )		10 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
Interval Dosage Unit Number (derived)		<hr/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:15

Name of Medication	KETOROLAC
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	CHOLECYSTECTOMY
Dose per administration	30
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 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 type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:15

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date ( <i>dd MMM yyyy</i> )		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date ( <i>dd MMM yyyy</i> )		10 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
Interval Dosage Unit Number (derived)		<hr/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:59:15

Name of Medication	DEXAMETHASONE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	CHOLECYSTECTOMY
Dose per administration	4
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 type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:59:15

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date ( <i>dd MMM yyyy</i> )		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date ( <i>dd MMM yyyy</i> )		10 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)	<hr/>	
Interval Dosage Unit Number (derived)	<hr/>	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:59:15

Name of Medication	LACTATED RIGORS
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	CHOLECYSTECTOMY
Dose per administration	1200
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 type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:59:15

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date ( <i>dd MMM yyyy</i> )		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date ( <i>dd MMM yyyy</i> )		10 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
Interval Dosage Unit Number (derived)		<hr/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:59:15

Name of Medication	PROPOFOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	CHOLITHIASISMIS/ CHOLECYSTECTOMY
Dose per administration	80
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 type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:59:15

	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 checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		10 OCT 2020
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
<hr/>		
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"/>	



US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:59:15

Name of Medication	LIDOCAINE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	CHOLITHIASISMIS/ CHOLECYSTECTOMY
Dose per administration	50
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 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 type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:59:15

	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 checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		10 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:59:15

Name of Medication	ROCURONIUM
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	CHOLITHIASISMIS/ CHOLECYSTECTOMY
Dose per administration	50
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 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 type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:59:15

	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 checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		10 OCT 2020
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
<hr/>		
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:59:15

Name of Medication	ZOFRAN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	CHOLITHIASISMIS/ CHOLECYSTECTOMY
Dose per administration	4
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 type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:59:15

	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 checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		10 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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"/>

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:59:15

Name of Medication	NEOSTIGMINE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	CHOLITHIASISMIS/ CHOLECYSTECTOMY
Dose per administration	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 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 type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:59:15

	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 checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		10 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:59:15

Name of Medication	ZOFRAN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	NAUSEA PREVENTION
Dose per administration	4
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 checked="" 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"/>

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:59:15

	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 <hr/>		
Start date ( <i>dd MMM yyyy</i> )		11 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date ( <i>dd MMM yyyy</i> )		12 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)	<hr/>	
Interval Dosage Unit Number (derived)	<hr/>	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:59:15

Name of Medication	MIDAZOLAM
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	CHOLITHIASISMIS/ CHOLECYSTECTOMY
Dose per administration	2
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 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 type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:59:15

	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 checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		10 OCT 2020
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
<hr/>		
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"/>	

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 10:59:15

Name of Medication	FENTANYL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	CHOLECYSTECTOMY
Dose per administration	100
Dose unit	mg <input 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 checked="" type="radio"/>
If dose unit is Other, specify	MCG
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 type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 10:59:15

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date ( <i>dd MMM yyyy</i> )		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date ( <i>dd MMM yyyy</i> )		10 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)	<hr/>	
Interval Dosage Unit Number (derived)	<hr/>	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 10:59:15

Name of Medication	FENTANYL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	CHOLECYSTECTOMY
Dose per administration	150
Dose unit	mg <input 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 checked="" type="radio"/>
If dose unit is Other, specify	MCG
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 type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 10:59:15

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date ( <i>dd MMM yyyy</i> )		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date ( <i>dd MMM yyyy</i> )		10 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
Interval Dosage Unit Number (derived)		<hr/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3362222

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:59:15

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3362222

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 10:59:15

Procedure/Surgery date ( <i>dd MMM</i> <i>yyyy</i> )	Procedure/Surgery	Indication	If indication is Other, specify
10 OCT 2020	CHOLECYSTECTOMY	Adverse Event	

US3362222

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:59:15

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

US3362222

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:59:15

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 ☐

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

SAEID	USA-US112-2020-MRNA-1273-P301000005
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:59:15

SAEID	USA-US112-2020-MRNA-1273-P301000005
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	26/OCT/2020 11:30
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

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:59:15

SAEID	USA-US112-2020-MRNA-1273-P301000005
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	03/NOV/2020 16:10
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

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:59:15

SAEID	USA-US112-2020-MRNA-1273-P301000005
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	04/NOV/2020 13:30
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



US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:59:15

SAEID	USA-US112-2020-MRNA-1273-P301000005
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/NOV/2020 13:31
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

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 10:59:15

SAEID	USA-US112-2020-MRNA-1273-P301000005
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	19/NOV/2020 14:32
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

US3362222 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

**US3362222**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:59:15**

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3362222'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	22 Aug 2020 13:09:14

US3362222

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:59:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:56:15

US3362222

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:59:15

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	05 Oct 2020 18:12:47
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	05 Oct 2020 18:11:17
User entered '22 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 18:11:17
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	03 Sep 2020 12:24:29
User entered '28 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 12:24:29
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	28 Aug 2020 21:58:12
User entered '22 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 13:09:15

US3362222

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	28 Aug 2020 21:56:15

**US3362222**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:59:15**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	28 Aug 2020 21:56:15



US3362222

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:15

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab for Visit1 Day1: Year of Birth (1979) recorded on this form does not match with the Year of birth (1969) reported in PPD Central lab. Please reconcile the correct date and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 09:08:47
User entered (b) (6) 1969' reason for change: Data Entry Error	RWS_ENDPOINT ENDPOINT (b) (4)	02 Nov 2020 16:50:31
Query 'Per GCL Lab Reconciliation: Swab for Visit1 Day1: Year of Birth (1979) recorded on this form does not match with the Year of birth (1969) reported in PPD Central lab. Please reconcile the correct date and update if confirmed. Else clarify, thank you.' answered with 'CORRECT YEAR OF BIRTH IS 1969. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 15:37:45
User opened query 'Per GCL Lab Reconciliation: Swab for Visit1 Day1: Year of Birth (1979) recorded on this form does not match with the Year of birth (1969) reported in PPD Central lab. Please reconcile the correct date and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 09:57:24
User entered (b) (6) 1979'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 13:09:16

US3362222

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:15

Age

Audit	User	Time (GMT)
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	02 Nov 2020 17:04:54
User entered '51' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	02 Nov 2020 17:04:54
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	02 Nov 2020 16:50:31
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	01 Sep 2020 17:13:54
User entered '41' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	01 Sep 2020 17:13:54
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	28 Aug 2020 21:58:12
User entered '51'	(b) (4), (b) (6) (b) (4), (b) (6)	28 Aug 2020 21:57:41

**US3362222**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:59:15**

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	28 Aug 2020 21:57:41

**US3362222**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:59:15**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '51'	System	02 Nov 2020 16:50:31
User entered '41'	System	28 Aug 2020 21:58:12

US3362222

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:15

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	(b) (4), (b) (6)	28 Aug 2020 21:57:41

US3362222

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:15

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	28 Aug 2020 21:57:41

US3362222

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:15

White

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	28 Aug 2020 21:57:41

US3362222

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:15

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 21:57:41



US3362222

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:15

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 21:57:41

US3362222

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:15

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 21:57:41

US3362222

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:15

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 21:57:41

US3362222

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:15

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 21:57:41

US3362222

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:15

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 21:57:41

US3362222

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:15

Unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 21:57:41

US3362222

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:15

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 21:57:41

US3362222

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:15

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 18:12:47
User entered '28 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 21:58:12



**US3362222**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	28 Aug 2020 21:58:12

**US3362222**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered '2020'	System	28 Aug 2020 21:58:12

US3362222

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:15

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	28 Aug 2020 21:58:12

US3362222

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:58:12

US3362222

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:15

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 21:58:12

US3362222

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:15

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 21:58:12

US3362222

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:15

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 21:58:12

US3362222

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:15

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	22 Aug 2020 13:09:15



**US3362222**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:59:15**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 21:58:30

US3362222

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:58:30

US3362222

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:59:15

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 19:08:19

US3362222

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:15

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per protocol pg 44, "Nonchildbearing" potential is defined as surgically sterile (history of bilateral tubal ligation, bilateral oophorectomy, hysterectomy). Please reconcile, thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 20:01:08
Query 'Per CDM: Per protocol pg 44, "Nonchildbearing" potential is defined as surgically sterile (history of bilateral tubal ligation, bilateral oophorectomy, hysterectomy). Please reconcile, thank you.' answered with 'updated childbearing potential' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 20:14:37
User opened query 'Per CDM: Per protocol pg 44, "Nonchildbearing" potential is defined as surgically sterile (history of bilateral tubal ligation, bilateral oophorectomy, hysterectomy). Please reconcile, thank you.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 18:53:58
User closed query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 18:47:23
User closed query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 18:38:01
Query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify.' answered with 'per protocol bilateral tubal ligation is not surgically sterile' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 13:48:47

US3362222

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:15

[Condition](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' answered with 'start and stop dates are the same' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 13:47:56
User opened query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 04:12:26
User opened query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 04:11:58
Query "'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration.	(b) (4), (b) (6)	24 Sep 2020 04:11:44
Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify."		
' canceled (Site from DM).		

US3362222

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:15

Condition

Audit	User	Time (GMT)
User opened query "'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration.   Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify.'" ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 04:11:35
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 19:10:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	31 Aug 2020 19:10:40
Data point term sent to Coder	System	31 Aug 2020 19:09:40
User entered 'BILATERAL TUBAL LIGATION'	(b) (4), (b) (6)	31 Aug 2020 19:09:11

US3362222

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Sep 2020 12:59:17
User entered 'UN UNK 2013' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 12:59:17
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Aug 2020 19:09:11
User entered 'UN 2013' (non-conformant).	(b) (4), (b) (6)	31 Aug 2020 19:09:11

US3362222

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 19:09:11



US3362222

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 19:09:11

US3362222

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'UN UNK 2013'	(b) (4), (b) (6)	31 Aug 2020 19:09:11

US3362222

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 19:09:11

**US3362222**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	01 Sep 2020 12:59:17
User entered empty.	System	31 Aug 2020 19:09:11

**US3362222**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered '2013'	System	01 Sep 2020 12:59:17
User entered empty.	System	31 Aug 2020 19:09:11

US3362222

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	31 Aug 2020 19:09:11

**US3362222**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered '2013'	System	31 Aug 2020 19:09:11

US3362222

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:15

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 18:55:07
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'See Con Med line 5 for medication for asthma ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 13:52:11
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 04:13:25
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:10:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:10:41
Data point term sent to Coder	System	31 Aug 2020 19:09:42
User entered 'ASTHMA'	(b) (4), (b) (6)	31 Aug 2020 19:09:37



US3362222

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'UN UNK 2014'	(b) (4), (b) (6)	31 Aug 2020 19:09:37

US3362222

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 19:09:37

US3362222

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 19:09:37

US3362222

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 19:09:37

US3362222

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 19:09:37

**US3362222**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	31 Aug 2020 19:09:37

**US3362222**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered '2014'	System	31 Aug 2020 19:09:37

**US3362222**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:09:37



**US3362222**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:09:37

US3362222

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:15

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 19:11:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 19:11:35
Data point term sent to Coder	System	31 Aug 2020 19:10:44
User entered 'MIGRAINE'	(b) (4), (b) (6)	31 Aug 2020 19:10:04

US3362222

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'UN UNK 1984'	(b) (4), (b) (6)	31 Aug 2020 19:10:04

US3362222

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 19:10:04

US3362222

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 19:10:04

US3362222

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 19:10:04

US3362222

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 19:10:04

**US3362222**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered 'Jan 1984'	System	31 Aug 2020 19:10:04



**US3362222**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered '1984'	System	31 Aug 2020 19:10:04

**US3362222**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:10:04

**US3362222**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:10:04

US3362222

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:15

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 18:55:35
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'See Con Med line 1 for medication for hypothyroidism' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 13:51:55
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 04:14:50
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:12:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:12:37
Data point term sent to Coder	System	31 Aug 2020 19:11:45
User entered 'HYPOTHYROIDISM'	(b) (4), (b) (6)	31 Aug 2020 19:10:51

US3362222

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015' reason for change:	Crystal Rowell (b) (4)	23 Oct 2020 19:21:32
Data Entry Error	(b) (4)	
User entered 'UN UNK 2019'	(b) (4), (b) (6)	31 Aug 2020 19:10:51

US3362222

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 19:10:51

US3362222

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 19:10:51

US3362222

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 19:10:51



US3362222

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 19:10:51

**US3362222**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	23 Oct 2020 19:21:32
User entered 'Jan 2019'	System	31 Aug 2020 19:10:51

**US3362222**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered '2015'	System	23 Oct 2020 19:21:32
User entered '2019'	System	31 Aug 2020 19:10:51

**US3362222**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:10:51

**US3362222**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:10:51

US3362222

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:15

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Acute and chronic thyroiditis, PT: Autoimmune thyroiditis, LLT: Hashimoto's thyroiditis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 15:25:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 15:25:22
Data point term sent to Coder	System	03 Nov 2020 15:24:48
Coding entries removed.	Crystal Rowell (b) (4) (b) (4)	03 Nov 2020 15:24:21
User entered 'Hashimoto's THYROIDITIS' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	03 Nov 2020 15:24:21
User closed query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary.	(b) (4), (b) (6)	08 Oct 2020 11:29:29
' (Site from DM).		
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Acute and chronic thyroiditis, PT: Autoimmune thyroiditis, LLT: Chronic lymphocytic thyroiditis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:57:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:57:37
Data point term sent to Coder	System	01 Oct 2020 13:56:02
Query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary.	(b) (4), (b) (6)	01 Oct 2020 13:55:17
' answered with 'UPDATED' (Site from DM).		
Coding entries removed.	(b) (4), (b) (6)	01 Oct 2020 13:55:11
User entered 'chronic lymphocytic thyroiditis' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 13:55:11
User opened query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary.	(b) (4), (b) (6)	24 Sep 2020 04:15:14
' (Site from DM).		

US3362222

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:15

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Acute and chronic thyroiditis, PT: Autoimmune thyroiditis, LLT: Hashimoto's disease - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 19:13:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 19:13:45
Data point term sent to Coder	System	31 Aug 2020 19:12:48
User entered 'HASHIMOTO'S'	(b) (4), (b) (6)	31 Aug 2020 19:12:13

US3362222

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'UN UNK 2014'	(b) (4), (b) (6)	31 Aug 2020 19:12:13



US3362222

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 19:12:13

US3362222

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 19:12:13

US3362222

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 19:12:13

US3362222

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 19:12:13

**US3362222**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	31 Aug 2020 19:12:13

**US3362222**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered '2014'	System	31 Aug 2020 19:12:13

**US3362222**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:12:13

**US3362222**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:12:13



US3362222

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:15

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Anorectal therapeutic procedures, PT: Anal fissure excision, LLT: Anal fissure excision - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:16:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:16:56
Data point term sent to Coder	System	31 Aug 2020 19:13:51
User entered 'ANAL FISSURE REPAIR'	(b) (4), (b) (6) (b) (4)	31 Aug 2020 19:13:12

US3362222

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'UN Jun 2019'	(b) (4), (b) (6)	31 Aug 2020 19:13:12

US3362222

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 19:13:12

US3362222

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 19:13:12

US3362222

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	31 Aug 2020 19:29:20
User entered 'UN Jun 2019' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 19:29:20
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	31 Aug 2020 19:13:12
User entered 'UN UNK 2019'	(b) (4), (b) (6)	31 Aug 2020 19:13:12

US3362222

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 19:13:12

US3362222

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'Jun 2019'	System	31 Aug 2020 19:13:12

**US3362222**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered '2019'	System	31 Aug 2020 19:13:12



**US3362222**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered 'Jun 2019'	System	31 Aug 2020 19:29:20
User entered 'Jan 2019'	System	31 Aug 2020 19:13:12

**US3362222**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered '2019'	System	31 Aug 2020 19:13:12

US3362222

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:15

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 19:16:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 19:16:57
Data point term sent to Coder	System	31 Aug 2020 19:13:52
User entered 'ANXIETY'	(b) (4), (b) (6)	31 Aug 2020 19:13:44

US3362222

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Aug 2020 19:29:01
User entered 'UN UNK 1984' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 19:29:01
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Aug 2020 19:13:44
User entered 'UN 1984' (non-conformant).	(b) (4), (b) (6)	31 Aug 2020 19:13:44

US3362222

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 19:13:44

US3362222

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 19:13:44

US3362222

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 19:13:44

US3362222

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 19:13:44



**US3362222**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered 'Jan 1984'	System	31 Aug 2020 19:29:01
User entered empty.	System	31 Aug 2020 19:13:44

**US3362222**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered '1984'	System	31 Aug 2020 19:29:01
User entered empty.	System	31 Aug 2020 19:13:44

**US3362222**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:13:44

**US3362222**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:13:44

US3362222

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:15

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:30:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:30:41
Data point term sent to Coder	System	31 Aug 2020 19:29:27
User entered 'DEPRESSION'	(b) (4), (b) (6) (b) (4)	31 Aug 2020 19:28:39

US3362222

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'UN UNK 1984'	(b) (4), (b) (6)	31 Aug 2020 19:28:39

US3362222

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 19:28:39

US3362222

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 19:28:39



US3362222

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 19:28:39

US3362222

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 19:28:39

**US3362222**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered 'Jan 1984'	System	31 Aug 2020 19:28:39

**US3362222**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered '1984'	System	31 Aug 2020 19:28:39

**US3362222**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:28:39

**US3362222**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:28:39

US3362222

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:59:15

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Dementia and amnestic conditions, HLT: Dementia NEC, PT: Pseudodementia, LLT: Pseudodementia - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 15:26:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 15:26:22
Data point term sent to Coder	System	03 Nov 2020 15:24:53
User entered 'pseudodementia'	Crystal Rowell (b) (4)	03 Nov 2020 15:24:49
	(b) (4)	

US3362222

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	03 Nov 2020 15:24:49



US3362222

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:59:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered 'I'	Crystal Rowell (b) (4) (b) (4)	03 Nov 2020 15:24:49

US3362222

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:59:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	03 Nov 2020 15:24:49

US3362222

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	03 Nov 2020 15:24:49

US3362222

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:59:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Crystal Rowell (b) (4) (b) (4)	03 Nov 2020 15:24:49

**US3362222**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 15:24:49

**US3362222**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 15:24:49

US3362222

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 15:24:49

**US3362222**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 15:24:49



US3362222

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 19:31:11

US3362222

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:15

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	05 Oct 2020 18:13:01
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	05 Oct 2020 18:13:01
User entered '22 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 18:13:01
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	05 Oct 2020 18:11:17
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	03 Sep 2020 12:24:29
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	03 Sep 2020 12:24:29
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	31 Aug 2020 19:32:55
User closed query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	31 Aug 2020 19:32:55
User entered '28 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 19:32:55
User opened query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	31 Aug 2020 19:31:11
User entered '22 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 19:31:11

US3362222

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered '15:53' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 19:33:37
User entered '08:23'	(b) (4), (b) (6)	31 Aug 2020 19:31:11

**US3362222**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered '22 Aug 2020 15:53'	System	05 Oct 2020 18:13:01
User entered '28 Aug 2020 15:53'	System	31 Aug 2020 19:33:37
User entered '28 Aug 2020 08:23'	System	31 Aug 2020 19:32:55
User entered '22 Aug 2020 08:23'	System	31 Aug 2020 19:31:11

US3362222

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered '162.6' cm	(b) (4), (b) (6)	31 Aug 2020 19:31:11
DataPoint set to visible.	System	28 Aug 2020 21:58:30

US3362222

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered '79.8' kg	(b) (4), (b) (6)	31 Aug 2020 19:31:11
DataPoint set to visible.	System	28 Aug 2020 21:58:30

**US3362222**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:15**

**BMI (xxx.x)**

Audit	User	Time (GMT)
User entered '30.18296'	System	31 Aug 2020 19:31:11
DataPoint set to visible.	System	28 Aug 2020 21:58:30

**US3362222**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:15**

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	31 Aug 2020 19:31:11
DataPoint set to visible.	System	28 Aug 2020 21:58:30



US3362222

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:15

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 07:51:30
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 18:41:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 18:41:35
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 12:46:41
User entered '36.8' C reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 19:32:55
User entered '37.1' C	(b) (4), (b) (6)	31 Aug 2020 19:31:11

US3362222

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:15

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 18:41:35
User entered 'Oral (Oral)'	(b) (4), (b) (6)	31 Aug 2020 19:31:11

US3362222

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:15

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 19:31:11

US3362222

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 18:41:35
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 19:32:55
User entered '63'	(b) (4), (b) (6)	31 Aug 2020 19:31:11

**US3362222**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:15**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Aug 2020 19:31:11

US3362222

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 18:41:35
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 19:32:55
User entered '14'	(b) (4), (b) (6)	31 Aug 2020 19:31:11

US3362222

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Aug 2020 19:31:11

US3362222

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 18:41:35
User entered '119'	(b) (4), (b) (6)	31 Aug 2020 19:31:11



**US3362222**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:15**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 19:31:11

US3362222

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 18:41:35
User entered '77' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 19:32:55
User entered '74'	(b) (4), (b) (6)	31 Aug 2020 19:31:11

**US3362222**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:15**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 19:31:11

US3362222

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 19:34:12

US3362222

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 18:13:08
User entered '28 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 19:34:12

US3362222

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User closed query 'Date of Assessment is after Date of Informed Consent. Please correct.' (Site from System).	System	05 Oct 2020 18:13:13
User entered '22 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 18:13:13
User opened query 'Date of Assessment is after Date of Informed Consent. Please correct.' (Site from System).	System	05 Oct 2020 18:12:47
User entered '28 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 19:36:05

US3362222

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:15

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
User closed query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	21 Oct 2020 17:59:22
User opened query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	21 Oct 2020 17:59:01
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 17:59:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 20:13:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 19:36:05

US3362222

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:15

If No, what is the reason?

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 17:59:22
User closed query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	15 Oct 2020 20:13:29
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 20:13:29
User opened query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	15 Oct 2020 20:13:25
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 19:36:05



US3362222

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:15

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 19:36:05

US3362222

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 17:59:22
User closed query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	15 Oct 2020 20:13:38
User entered 'un UNK 2013' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 20:13:38
User opened query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	15 Oct 2020 20:13:29
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 19:36:05

US3362222

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:15

Date of surgery unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 19:36:05

US3362222

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 19:36:05

US3362222

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:15

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 19:36:05

US3362222

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:59:15

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM re-query: Please be aware that bilateral tubal ligation is considered under surgically sterile procedure. Please review protocol version 4, page 44 and Inclusion Criteria. Please clarify why subject performed pregnancy test, when subject is surgically sterile. Thank you!' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 14:47:16
Query 'Per CDM re-query: Please be aware that bilateral tubal ligation is considered under surgically sterile procedure. Please review protocol version 4, page 44 and Inclusion Criteria. Please clarify why subject performed pregnancy test, when subject is surgically sterile. Thank you!' answered with 'please note that CTM and MM clarified in epip that a BTL is a form of contraception not surgically sterile, it conflicts with the I/E , this is entered as directed by Epip ' (Site from DM).	Crystal Rowell (b) (4)	23 Oct 2020 19:27:26
User opened query 'Per CDM re-query: Please be aware that bilateral tubal ligation is considered under surgically sterile procedure. Please review protocol version 4, page 44 and Inclusion Criteria. Please clarify why subject performed pregnancy test, when subject is surgically sterile. Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 07:44:13
User closed query 'Per CDM: Subject is with non-childbearing potential, however pregnancy test was performed. Please clarify why pregnancy test was performed. Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 07:44:13
Query 'Per CDM: Subject is with non-childbearing potential, however pregnancy test was performed. Please clarify why pregnancy test was performed. Thank you!' answered with 'bilateral tubal ligation per protocol isnt classified as sterile ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 17:58:49
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 17:50:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 17:50:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 17:50:02

US3362222

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:59:15

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 17:49:32
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 17:49:32
User closed query 'Was the pregnancy test performed is No, however data has been provided below. Please correct.' (Site from System).	System	21 Oct 2020 17:49:14
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 17:49:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 17:49:10
User opened query 'Was the pregnancy test performed is No, however data has been provided below. Please correct.' (Site from System).	System	21 Oct 2020 17:49:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 17:49:10
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 17:48:44
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 17:48:44
User opened query 'Per CDM: Subject is with non-childbearing potential, however pregnancy test was performed. Please clarify why pregnancy test was performed. Thank you!' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 11:41:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:03:16

US3362222

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:59:15

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 17:50:02
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 17:49:10
User entered '22 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 18:13:21
User entered '28 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 20:03:16



US3362222

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:59:15

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 17:50:02
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 17:49:14
User entered 'Urine (URINE)'	(b) (4), (b) (6)	31 Aug 2020 20:03:16

US3362222

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:59:15

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 17:50:02
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 17:49:10
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 20:03:22
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 20:03:22
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 20:03:16
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:03:16

US3362222

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:59:15

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 16:08:10
Query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly. ' answered with 'NO FSH WAS COLLECTED ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:17:47
User opened query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 18:35:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 17:57:19
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 17:49:10
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:03:16

**US3362222**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 10:59:15**

[Collection date](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 20:17:28
User entered '22 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 17:57:19
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:03:16

US3362222

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:59:15

[Collection time](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 20:17:28
User entered '08:28' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 17:57:19
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:03:16

**US3362222**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 20:17:28
User entered '22 Aug 2020 08:28'	System	21 Oct 2020 17:57:19
User entered empty.	System	31 Aug 2020 20:03:16

US3362222

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:05:32

US3362222

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:05:32



US3362222

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:15

**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)'	(b) (4), (b) (6)	31 Aug 2020 20:05:32

US3362222

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:05:32

US3362222

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:05:32

US3362222

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:05:32

US3362222

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:15

**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)'	(b) (4), (b) (6)	31 Aug 2020 20:05:32

US3362222

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:15

**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)'	(b) (4), (b) (6)	31 Aug 2020 20:05:32

US3362222

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:05:32

US3362222

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:15

**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)'	(b) (4), (b) (6)	31 Aug 2020 20:05:32



US3362222

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:15

**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)'	(b) (4), (b) (6)	31 Aug 2020 20:05:32

US3362222

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:15

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:05:32

US3362222

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:15

[Specify](#)

Audit	User	Time (GMT)
User entered 'PART TIME REPORTER (b) (6) COMES INTO CONTACT WITH PEOPLE DAILY'	(b) (4), (b) (6)	31 Aug 2020 20:05:32

US3362222

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:15

**No Risk Identified**

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:05:32

US3362222

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:05:32

US3362222

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:15

**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'	(b) (4), (b) (6)	31 Aug 2020 20:05:32

US3362222

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	31 Aug 2020 20:05:32

US3362222

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:15

**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'	(b) (4), (b) (6)	31 Aug 2020 20:05:32



US3362222

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:05:32

US3362222

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:15

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:05:32

US3362222

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:15

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:05:32

US3362222

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:59:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:06:31

US3362222

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered '28 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 20:06:31

US3362222

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	31 Aug 2020 20:06:31

**US3362222**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:59:15**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	31 Aug 2020 20:06:31

US3362222

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered '28 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	28 Aug 2020 21:19:32



US3362222

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:15

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '145056'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	28 Aug 2020 21:19:32

US3362222

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	28 Aug 2020 21:19:32

US3362222

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:15

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 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:07:05

US3362222

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:15

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)	31 Aug 2020 20:07:05

US3362222

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:07:05

US3362222

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:15

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:07:05

US3362222

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:15

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:07:05

US3362222

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 18:13:33
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 02:17:26
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:17:22



US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:15

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 07:51:35
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	(b) (4), (b) (6)	24 Sep 2020 18:48:32
answered with 'updated' (Site from DM).		
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 18:48:28
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 12:46:29
User entered '162.6' cm	(b) (4), (b) (6)	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:15

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 18:48:28
User entered '79.8' kg	(b) (4), (b) (6)	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:15

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 07:51:35
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	(b) (4), (b) (6)	24 Sep 2020 18:48:32
answered with 'updated' (Site from DM).		
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 18:48:28
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 12:46:29
User entered '162.6' cm	(b) (4), (b) (6)	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:15

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 18:48:28
User entered '79.8' kg	(b) (4), (b) (6)	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered '15:53'	(b) (4), (b) (6)	31 Aug 2020 20:09:33



**US3362222**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 15:53'	System	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	(b) (4), (b) (6)	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '70'	(b) (4), (b) (6)	31 Aug 2020 20:09:33

**US3362222**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:59:15**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered '18'	(b) (4), (b) (6)	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Aug 2020 20:09:33



US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '126'	(b) (4), (b) (6)	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '77'	(b) (4), (b) (6)	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:15

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 07:51:35
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	(b) (4), (b) (6)	24 Sep 2020 18:48:32
answered with 'updated' (Site from DM).		
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 18:48:28
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 12:46:29
User entered '162.6' cm	(b) (4), (b) (6)	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:15

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 18:48:28
User entered '79.8' kg	(b) (4), (b) (6)	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:09:33



US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered '17:21'	(b) (4), (b) (6)	31 Aug 2020 20:09:33

**US3362222**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 17:21'	System	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	(b) (4), (b) (6)	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '72'	(b) (4), (b) (6)	31 Aug 2020 20:09:33

**US3362222**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:59:15**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Aug 2020 20:09:33



US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered '18'	(b) (4), (b) (6)	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '113'	(b) (4), (b) (6)	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '78'	(b) (4), (b) (6)	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 20:09:33

US3362222

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:15

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:09:45

US3362222

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 20:09:45



US3362222

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:59:15

Was the pregnancy test performed?

Audit	User	Time (GMT)
User closed query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 12:23:52
Query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' answered with 'updated per query' (Site from DM).	Amy Thomassie (b) (4)	09 Sep 2020 00:48:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	09 Sep 2020 00:48:45
User opened query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 10:26:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:10:20

US3362222

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:59:15

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	09 Sep 2020 00:48:45
User entered '28 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 20:10:20

US3362222

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:59:15

[Test performed](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	09 Sep 2020 00:48:45
User entered 'Urine (URINE)'	(b) (4), (b) (6)	31 Aug 2020 20:10:20

US3362222

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:59:15

[Result](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	09 Sep 2020 00:48:45
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	31 Aug 2020 20:10:20

US3362222

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:59:15

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	09 Sep 2020 00:48:45
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:10:20

US3362222

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:59:15

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:10:20

US3362222

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:59:15

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:10:20

**US3362222**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 20:10:20



US3362222

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:59:12

US3362222

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:15

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 21:59:12

US3362222

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:15

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)	28 Aug 2020 21:59:12

US3362222

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:15

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 21:59:12

US3362222

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:15

What was the treatment date? (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 21:59:12

US3362222

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered '16:11'	(b) (4), (b) (6)	28 Aug 2020 21:59:12

**US3362222**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 16:11'	System	28 Aug 2020 21:59:12

US3362222

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	28 Aug 2020 21:59:12



US3362222

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	28 Aug 2020 21:59:12

US3362222

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 21:59:12

US3362222

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:11:10

US3362222

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 20:11:10

US3362222

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '16:07' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 18:14:33
User entered '16:08' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 18:14:01
User entered '16:07'	(b) (4), (b) (6)	31 Aug 2020 20:11:10

**US3362222**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 16:07'	System	05 Oct 2020 18:14:33
User entered '28 Aug 2020 16:08'	System	05 Oct 2020 18:14:01
User entered '28 Aug 2020 16:07'	System	31 Aug 2020 20:11:10

US3362222

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:59:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 20:11:44

US3362222

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:15

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	31 Aug 2020 20:11:44



US3362222

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:11:44

US3362222

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '16:08'	(b) (4), (b) (6)	31 Aug 2020 20:11:44

**US3362222**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 16:08'	System	31 Aug 2020 20:11:44

US3362222

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:15

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	31 Aug 2020 20:11:44

US3362222

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:11:44

US3362222

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:11:44

**US3362222**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 20:11:44

US3362222

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:11:50



**US3362222**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:59:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Aug 2020 20:11:50

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 21:59:12

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T17:17:21', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'e3f4079e-8e4e-4472-ae23-08219ed17c6f'	System	28 Aug 2020 22:17:51
User entered 'Yes (Y)'	System	28 Aug 2020 22:17:51

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T17:17:28', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'e3f4079e-8e4e-4472-ae23-08219ed17c6f'	System	28 Aug 2020 22:17:51
User entered '98.3'	System	28 Aug 2020 22:17:51

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T17:17:35', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'e3f4079e-8e4e-4472-ae23-08219ed17c6f'	System	28 Aug 2020 22:17:51
User entered 'No (N)'	System	28 Aug 2020 22:17:51

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T17:17:46', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'e3f4079e-8e4e-4472-ae23-08219ed17c6f'	System	28 Aug 2020 22:17:51
User entered '28 Aug 2020 17:17'	System	28 Aug 2020 22:17:51

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 16:31'	System	28 Aug 2020 21:59:12

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 19:01'	System	28 Aug 2020 21:59:12



**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 21:59:12

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T22:36:30', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '584d1ff3-9e60-4abe-bb23-28f2413a595e'	System	29 Aug 2020 03:36:51
User entered 'Yes (Y)'	System	29 Aug 2020 03:36:51

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T22:36:35', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '584d1ff3-9e60-4abe-bb23-28f2413a595e'	System	29 Aug 2020 03:36:51
User entered '97.8'	System	29 Aug 2020 03:36:51

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T22:36:42', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '584d1ff3-9e60-4abe-bb23-28f2413a595e'	System	29 Aug 2020 03:36:51
User entered 'No (N)'	System	29 Aug 2020 03:36:51

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T22:36:49', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '584d1ff3-9e60-4abe-bb23-28f2413a595e'	System	29 Aug 2020 03:36:51
User entered '28 Aug 2020 22:36'	System	29 Aug 2020 03:36:51

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 19:56'	System	28 Aug 2020 21:59:12

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 21:59:12

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered 'Day 2'	System	28 Aug 2020 21:59:12



US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:59:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-29T21:13:40', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'a70270c8-31b1-4375-be96-262fd8bf1b2e'	System	30 Aug 2020 02:15:17
User entered 'Yes (Y)'	System	30 Aug 2020 02:15:17

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:59:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-29T21:14:57', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'a70270c8-31b1-4375-be96-262fd8bf1b2e'	System	30 Aug 2020 02:15:17
User entered '98.6'	System	30 Aug 2020 02:15:17

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-29T21:15:01', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'a70270c8-31b1-4375-be96-262fd8bf1b2e'	System	30 Aug 2020 02:15:17
User entered 'No (N)'	System	30 Aug 2020 02:15:17

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-29T21:15:13', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'a70270c8-31b1-4375-be96-262fd8bf1b2e'	System	30 Aug 2020 02:15:17
User entered '29 Aug 2020 21:15'	System	30 Aug 2020 02:15:17

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 21:59:12

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 21:59:12

**US3362222**

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

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered 'Day 3'	System	28 Aug 2020 21:59:12

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-30T20:40:49', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '5bf530f7-adf4-44bb-9fcb-a8cce837f66d'	System	31 Aug 2020 01:41:21
User entered 'Yes (Y)'	System	31 Aug 2020 01:41:21



US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-30T20:40:57', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '5bf530f7-adf4-44bb-9fcb-a8cce837f66d'	System	31 Aug 2020 01:41:21
User entered '99.0'	System	31 Aug 2020 01:41:21

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-30T20:41:00', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '5bf530f7-adf4-44bb-9fcb-a8cce837f66d'	System	31 Aug 2020 01:41:21
User entered 'Yes (Y)'	System	31 Aug 2020 01:41:21

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 10:28:26
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant was contacted ' (Site from System).	Amy Thomassie (b) (4)	12 Sep 2020 16:39:05
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	31 Aug 2020 01:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-30T20:41:09', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '5bf530f7-adf4-44bb-9fcb-a8cce837f66d'	System	31 Aug 2020 01:41:21
User entered '1'	System	31 Aug 2020 01:41:21

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:15

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-30T20:41:09', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '5bf530f7-adf4-44bb-9fcb-a8cce837f66d' User entered '0'	System	31 Aug 2020 01:41:21

**US3362222**

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

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-30T20:41:18', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '5bf530f7-adf4-44bb-9fcb-a8cce837f66d'	System	31 Aug 2020 01:41:21
User entered '30 Aug 2020 20:41'	System	31 Aug 2020 01:41:21

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 21:59:12

**US3362222**

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

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 21:59:12

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered 'Day 4'	System	28 Aug 2020 21:59:12



US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:59:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-31T23:26:54', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'd53beb99-3744-4580-835e-a589874eeefd'	System	01 Sep 2020 04:27:23
User entered 'Yes (Y)'	System	01 Sep 2020 04:27:23

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:59:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-31T23:27:00', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'd53beb99-3744-4580-835e-a589874eeefd' User entered '97.1'	System	01 Sep 2020 04:27:23
	System	01 Sep 2020 04:27:23

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-31T23:27:14', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'd53beb99-3744-4580-835e-a589874eeefd'	System	01 Sep 2020 04:27:23
User entered 'No (N)'	System	01 Sep 2020 04:27:23

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-31T23:27:17', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'd53beb99-3744-4580-835e-a589874eeefd' User entered '31 Aug 2020 23:27'	System	01 Sep 2020 04:27:23
	System	01 Sep 2020 04:27:23

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:59:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 21:59:12

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:59:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 21:59:12

**US3362222**

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

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered 'Day 5'	System	28 Aug 2020 21:59:12

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:59:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-02T02:38:46', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'fa5b7468-b574-437d-a4f7-f73a1818675a' User entered 'Yes (Y)'	System	02 Sep 2020 07:39:01
	System	02 Sep 2020 07:39:01



US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:59:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-02T02:38:52', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'fa5b7468-b574-437d-a4f7-f73a1818675a'	System	02 Sep 2020 07:39:01
User entered '96.8'	System	02 Sep 2020 07:39:01

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-02T02:38:56', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'fa5b7468-b574-437d-a4f7-f73a1818675a'	System	02 Sep 2020 07:39:01
User entered 'No (N)'	System	02 Sep 2020 07:39:01

**US3362222**

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

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-02T02:39:00', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'fa5b7468-b574-437d-a4f7-f73a1818675a'	System	02 Sep 2020 07:39:01
User entered '02 Sep 2020 02:39'	System	02 Sep 2020 07:39:01

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:59:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 21:59:12

**US3362222**

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

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 21:59:12

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered 'Day 6'	System	28 Aug 2020 21:59:12

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:59:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T01:58:41', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '4d47cea9-cd3b-42e6-8d43-3f4c8a632f2c'	System	03 Sep 2020 06:59:52
User entered 'Yes (Y)'	System	03 Sep 2020 06:59:52

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:59:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T01:59:42', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '4d47cea9-cd3b-42e6-8d43-3f4c8a632f2c' User entered '97.3'	System	03 Sep 2020 06:59:52
	System	03 Sep 2020 06:59:52



US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T01:59:46', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '4d47cea9-cd3b-42e6-8d43-3f4c8a632f2c'	System	03 Sep 2020 06:59:52
User entered 'No (N)'	System	03 Sep 2020 06:59:52

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T01:59:49', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '4d47cea9-cd3b-42e6-8d43-3f4c8a632f2c'	System	03 Sep 2020 06:59:52
User entered '03 Sep 2020 01:59'	System	03 Sep 2020 06:59:52

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 21:59:12

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 21:59:12

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered 'Day 7'	System	28 Aug 2020 21:59:12

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:59:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T23:46:15', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '8af66a71-3e0b-4f9d-88ad-0c04e467f3ed'	System	04 Sep 2020 04:46:49
User entered 'Yes (Y)'	System	04 Sep 2020 04:46:49

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:59:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T23:46:38', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '8af66a71-3e0b-4f9d-88ad-0c04e467f3ed' User entered '97.3'	System	04 Sep 2020 04:46:49

US3362222

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T23:46:41', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '8af66a71-3e0b-4f9d-88ad-0c04e467f3ed'	System	04 Sep 2020 04:46:49
User entered 'No (N)'	System	04 Sep 2020 04:46:49



**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T23:46:45', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '8af66a71-3e0b-4f9d-88ad-0c04e467f3ed'	System	04 Sep 2020 04:46:49
User entered '03 Sep 2020 23:46'	System	04 Sep 2020 04:46:49

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 21:59:12

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 21:59:12

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 21:59:12

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T17:18:17', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'df0ce444-00fe-4d83-b248-2784fd92fdcb'	System	28 Aug 2020 22:18:38
User entered 'None (1)'	System	28 Aug 2020 22:18:38

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T17:18:21', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'df0ce444-00fe-4d83-b248-2784fd92fdcb'	System	28 Aug 2020 22:18:38
User entered 'No (N)'	System	28 Aug 2020 22:18:38

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T17:18:25', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'df0ce444-00fe-4d83-b248-2784fd92fdcb'	System	28 Aug 2020 22:18:38
User entered 'No (N)'	System	28 Aug 2020 22:18:38

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T17:18:32', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'df0ce444-00fe-4d83-b248-2784fd92fdcb'	System	28 Aug 2020 22:18:38
User entered 'None (1)'	System	28 Aug 2020 22:18:38



**US3362222**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T17:18:36', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'df0ce444-00fe-4d83-b248-2784fd92fdcb'	System	28 Aug 2020 22:18:38
User entered '28 Aug 2020 17:18'	System	28 Aug 2020 22:18:38

**US3362222**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 16:31'	System	28 Aug 2020 21:59:12

**US3362222**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 19:01'	System	28 Aug 2020 21:59:12

**US3362222**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 21:59:12

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T22:37:11', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'b4744ec5-6ac0-4ade-acd2-dcfa6aa02189'	System	29 Aug 2020 03:37:50
User entered 'None (1)'	System	29 Aug 2020 03:37:50

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T22:37:14', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'b4744ec5-6ac0-4ade-acd2-dcfa6aa02189'	System	29 Aug 2020 03:37:50
User entered 'No (N)'	System	29 Aug 2020 03:37:50

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T22:37:23', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'b4744ec5-6ac0-4ade-acd2-dcfa6aa02189'	System	29 Aug 2020 03:37:50
User entered 'No (N)'	System	29 Aug 2020 03:37:50

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T22:37:45', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'b4744ec5-6ac0-4ade-acd2-dcfa6aa02189'	System	29 Aug 2020 03:37:50
User entered 'None (1)'	System	29 Aug 2020 03:37:50



**US3362222**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T22:37:49', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'b4744ec5-6ac0-4ade-acd2-dcfa6aa02189'	System	29 Aug 2020 03:37:50
User entered '28 Aug 2020 22:37'	System	29 Aug 2020 03:37:50

**US3362222**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 19:56'	System	28 Aug 2020 21:59:12

**US3362222**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 21:59:12

**US3362222**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered 'Day 2'	System	28 Aug 2020 21:59:12

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-29T21:10:05', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '40f2b0e0-36a6-42f6-adbf-9bb9ae47812f'	System	30 Aug 2020 02:11:38
User entered 'Does not interfere with activity (2)'	System	30 Aug 2020 02:11:38

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:59:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-29T21:10:19', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '40f2b0e0-36a6-42f6-adbf-9bb9ae47812f'	System	30 Aug 2020 02:11:38
User entered 'No (N)'	System	30 Aug 2020 02:11:38

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-29T21:11:20', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '40f2b0e0-36a6-42f6-adbf-9bb9ae47812f'	System	30 Aug 2020 02:11:38
User entered 'No (N)'	System	30 Aug 2020 02:11:38

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-29T21:11:27', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '40f2b0e0-36a6-42f6-adbf-9bb9ae47812f'	System	30 Aug 2020 02:11:38
User entered 'Does not interfere with activity (2)'	System	30 Aug 2020 02:11:38



**US3362222**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-29T21:11:35', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '40f2b0e0-36a6-42f6-adbf-9bb9ae47812f'	System	30 Aug 2020 02:11:38
User entered '29 Aug 2020 21:11'	System	30 Aug 2020 02:11:38

**US3362222**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 21:59:12

**US3362222**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 21:59:12

**US3362222**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered 'Day 3'	System	28 Aug 2020 21:59:12

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-30T20:41:45', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '33a33897-c291-477a-a48f-ea4c1e24655e'	System	31 Aug 2020 01:42:17
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	31 Aug 2020 01:42:17

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-30T20:41:48', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '33a33897-c291-477a-a48f-ea4c1e24655e'	System	31 Aug 2020 01:42:17
User entered 'No (N)'	System	31 Aug 2020 01:42:17

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-30T20:41:51', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '33a33897-c291-477a-a48f-ea4c1e24655e'	System	31 Aug 2020 01:42:17
User entered 'Yes (Y)'	System	31 Aug 2020 01:42:17

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:15

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-30T20:42:02', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '33a33897-c291-477a-a48f-ea4c1e24655e' User entered '6'	System	31 Aug 2020 01:42:17
	System	31 Aug 2020 01:42:17



US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-30T20:42:12', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '33a33897-c291-477a-a48f-ea4c1e24655e'	System	31 Aug 2020 01:42:17
User entered 'Does not interfere with activity (2)'	System	31 Aug 2020 01:42:17

**US3362222**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-30T20:42:14', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '33a33897-c291-477a-a48f-ea4c1e24655e'	System	31 Aug 2020 01:42:17
User entered '30 Aug 2020 20:42'	System	31 Aug 2020 01:42:17

**US3362222**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 21:59:12

**US3362222**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 21:59:12

**US3362222**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered 'Day 4'	System	28 Aug 2020 21:59:12

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-31T23:24:27', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '64eb1e9e-9090-40aa-a3d6-5a2f9799fdf0'	System	01 Sep 2020 04:25:04
User entered 'None (1)'	System	01 Sep 2020 04:25:04

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:59:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-31T23:24:29', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '64eb1e9e-9090-40aa-a3d6-5a2f9799fdf0'	System	01 Sep 2020 04:25:04
User entered 'No (N)'	System	01 Sep 2020 04:25:04

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-31T23:24:39', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '64eb1e9e-9090-40aa-a3d6-5a2f9799fdf0'	System	01 Sep 2020 04:25:04
User entered 'No (N)'	System	01 Sep 2020 04:25:04



US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-31T23:24:49', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '64eb1e9e-9090-40aa-a3d6-5a2f9799fdf0'	System	01 Sep 2020 04:25:04
User entered 'None (1)'	System	01 Sep 2020 04:25:04

**US3362222**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-31T23:25:00', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '64eb1e9e-9090-40aa-a3d6-5a2f9799fdf0'	System	01 Sep 2020 04:25:04
User entered '31 Aug 2020 23:25'	System	01 Sep 2020 04:25:04

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:59:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 21:59:12

**US3362222**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 21:59:12

**US3362222**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered 'Day 5'	System	28 Aug 2020 21:59:12

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-02T02:37:09', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '705d794d-67f2-4bb8-bc7d-db8538b9e1e2'	System	02 Sep 2020 07:37:32
User entered 'None (1)'	System	02 Sep 2020 07:37:32

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:59:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-02T02:37:13', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '705d794d-67f2-4bb8-bc7d-db8538b9e1e2'	System	02 Sep 2020 07:37:32
User entered 'No (N)'	System	02 Sep 2020 07:37:32

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-02T02:37:21', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '705d794d-67f2-4bb8-bc7d-db8538b9e1e2'	System	02 Sep 2020 07:37:32
User entered 'No (N)'	System	02 Sep 2020 07:37:32



US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-02T02:37:27', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '705d794d-67f2-4bb8-bc7d-db8538b9e1e2'	System	02 Sep 2020 07:37:32
User entered 'None (1)'	System	02 Sep 2020 07:37:32

**US3362222**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-02T02:37:30', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '705d794d-67f2-4bb8-bc7d-db8538b9e1e2'	System	02 Sep 2020 07:37:32
User entered '02 Sep 2020 02:37'	System	02 Sep 2020 07:37:32

**US3362222**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 21:59:12

**US3362222**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 21:59:12

**US3362222**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered 'Day 6'	System	28 Aug 2020 21:59:12

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T01:59:54', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '6955aa69-10ed-45e7-84a3-f158bdac0ce4'	System	03 Sep 2020 07:00:17
User entered 'None (1)'	System	03 Sep 2020 07:00:17

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:59:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T01:59:58', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '6955aa69-10ed-45e7-84a3-f158bdac0ce4'	System	03 Sep 2020 07:00:17
User entered 'No (N)'	System	03 Sep 2020 07:00:17

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T02:00:06', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '6955aa69-10ed-45e7-84a3-f158bdac0ce4'	System	03 Sep 2020 07:00:17
User entered 'No (N)'	System	03 Sep 2020 07:00:17



US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T02:00:13', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '6955aa69-10ed-45e7-84a3-f158bdac0ce4'	System	03 Sep 2020 07:00:17
User entered 'None (1)'	System	03 Sep 2020 07:00:17

**US3362222**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T02:00:16', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '6955aa69-10ed-45e7-84a3-f158bdac0ce4'	System	03 Sep 2020 07:00:17
User entered '03 Sep 2020 02:00'	System	03 Sep 2020 07:00:17

**US3362222**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 21:59:12

**US3362222**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 21:59:12

**US3362222**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered 'Day 7'	System	28 Aug 2020 21:59:12

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T23:45:30', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'b94ce996-4d28-4b59-8f95-47baf03e2c77'	System	04 Sep 2020 04:45:44
User entered 'None (1)'	System	04 Sep 2020 04:45:44

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:59:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T23:45:34', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'b94ce996-4d28-4b59-8f95-47baf03e2c77'	System	04 Sep 2020 04:45:44
User entered 'No (N)'	System	04 Sep 2020 04:45:44

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T23:45:38', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'b94ce996-4d28-4b59-8f95-47baf03e2c77'	System	04 Sep 2020 04:45:44
User entered 'No (N)'	System	04 Sep 2020 04:45:44



US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T23:45:40', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'b94ce996-4d28-4b59-8f95-47baf03e2c77'	System	04 Sep 2020 04:45:44
User entered 'None (1)'	System	04 Sep 2020 04:45:44

**US3362222**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T23:45:43', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'b94ce996-4d28-4b59-8f95-47baf03e2c77'	System	04 Sep 2020 04:45:44
User entered '03 Sep 2020 23:45'	System	04 Sep 2020 04:45:44

US3362222

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:59:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 21:59:12

**US3362222**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 21:59:12

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 21:59:12

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T17:18:52', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '0f1ee581-04bd-4acd-8254-6522255479a1'	System	28 Aug 2020 22:19:45
User entered 'None (0)'	System	28 Aug 2020 22:19:45

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T17:19:05', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '0f1ee581-04bd-4acd-8254-6522255479a1'	System	28 Aug 2020 22:19:45
User entered 'None (0)'	System	28 Aug 2020 22:19:45

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T17:19:10', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '0f1ee581-04bd-4acd-8254-6522255479a1'	System	28 Aug 2020 22:19:45
User entered 'None (0)'	System	28 Aug 2020 22:19:45



**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T17:19:20', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '0f1ee581-04bd-4acd-8254-6522255479a1'	System	28 Aug 2020 22:19:45
User entered 'None (0)'	System	28 Aug 2020 22:19:45

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T17:19:22', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '0f1ee581-04bd-4acd-8254-6522255479a1'	System	28 Aug 2020 22:19:45
User entered 'None (0)'	System	28 Aug 2020 22:19:45

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T17:19:31', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '0f1ee581-04bd-4acd-8254-6522255479a1'	System	28 Aug 2020 22:19:45
User entered 'None (0)'	System	28 Aug 2020 22:19:45

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T17:19:37', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '0f1ee581-04bd-4acd-8254-6522255479a1'	System	28 Aug 2020 22:19:45
User entered 'No (N)'	System	28 Aug 2020 22:19:45

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T17:19:41', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '0f1ee581-04bd-4acd-8254-6522255479a1'	System	28 Aug 2020 22:19:45
User entered '28 Aug 2020 17:19'	System	28 Aug 2020 22:19:45

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 16:31'	System	28 Aug 2020 21:59:12

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 19:01'	System	28 Aug 2020 21:59:12

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 21:59:12



**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T22:37:56', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '38417db5-8551-4596-96a5-076f30ff31ef'	System	29 Aug 2020 03:38:18
User entered 'None (0)'	System	29 Aug 2020 03:38:18

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T22:37:59', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '38417db5-8551-4596-96a5-076f30ff31ef'	System	29 Aug 2020 03:38:18
User entered 'None (0)'	System	29 Aug 2020 03:38:18

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T22:38:01', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '38417db5-8551-4596-96a5-076f30ff31ef'	System	29 Aug 2020 03:38:18
User entered 'None (0)'	System	29 Aug 2020 03:38:18

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T22:38:04', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '38417db5-8551-4596-96a5-076f30ff31ef'	System	29 Aug 2020 03:38:18
User entered 'None (0)'	System	29 Aug 2020 03:38:18

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T22:38:06', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '38417db5-8551-4596-96a5-076f30ff31ef'	System	29 Aug 2020 03:38:18
User entered 'None (0)'	System	29 Aug 2020 03:38:18

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T22:38:08', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '38417db5-8551-4596-96a5-076f30ff31ef'	System	29 Aug 2020 03:38:18
User entered 'None (0)'	System	29 Aug 2020 03:38:18

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T22:38:12', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '38417db5-8551-4596-96a5-076f30ff31ef'	System	29 Aug 2020 03:38:18
User entered 'No (N)'	System	29 Aug 2020 03:38:18

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-28T22:38:15', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '38417db5-8551-4596-96a5-076f30ff31ef'	System	29 Aug 2020 03:38:18
User entered '28 Aug 2020 22:38'	System	29 Aug 2020 03:38:18



US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 19:56'	System	28 Aug 2020 21:59:12

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 21:59:12

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered 'Day 2'	System	28 Aug 2020 21:59:12

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-29T21:11:46', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '3e485d25-8ddf-4a04-9f6e-4e7721e9f1bb'	System	30 Aug 2020 02:15:54
User entered 'None (0)'	System	30 Aug 2020 02:15:54

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-29T21:11:53', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '3e485d25-8ddf-4a04-9f6e-4e7721e9f1bb'	System	30 Aug 2020 02:15:54
User entered 'Some interference with activity (2)'	System	30 Aug 2020 02:15:54

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:59:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-29T21:11:59', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '3e485d25-8ddf-4a04-9f6e-4e7721e9f1bb'	System	30 Aug 2020 02:15:54
User entered 'Some interference with activity (2)'	System	30 Aug 2020 02:15:54

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:59:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-29T21:12:05', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '3e485d25-8ddf-4a04-9f6e-4e7721e9f1bb'	System	30 Aug 2020 02:15:54
User entered 'Some interference with activity (2)'	System	30 Aug 2020 02:15:54

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-29T21:12:09', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '3e485d25-8ddf-4a04-9f6e-4e7721e9f1bb'	System	30 Aug 2020 02:15:54
User entered 'None (0)'	System	30 Aug 2020 02:15:54



**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-29T21:12:16', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '3e485d25-8ddf-4a04-9f6e-4e7721e9f1bb'	System	30 Aug 2020 02:15:54
User entered 'None (0)'	System	30 Aug 2020 02:15:54

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-29T21:15:25', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '3e485d25-8ddf-4a04-9f6e-4e7721e9f1bb'	System	30 Aug 2020 02:15:54
User entered 'No (N)'	System	30 Aug 2020 02:15:54

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-29T21:15:49', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '3e485d25-8ddf-4a04-9f6e-4e7721e9f1bb'	System	30 Aug 2020 02:15:54
User entered '29 Aug 2020 21:15'	System	30 Aug 2020 02:15:54

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 21:59:12

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 21:59:12

**US3362222**

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

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered 'Day 3'	System	28 Aug 2020 21:59:12

**US3362222**

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

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-30T20:42:27', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '93918978-6e7a-4636-9cc7-5da8abcdf459'	System	31 Aug 2020 01:43:03
User entered 'No interference with activity (1)'	System	31 Aug 2020 01:43:03

**US3362222**

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

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-30T20:42:32', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '93918978-6e7a-4636-9cc7-5da8abcdf459'	System	31 Aug 2020 01:43:03
User entered 'Some interference with activity (2)'	System	31 Aug 2020 01:43:03



**US3362222**

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

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-30T20:42:39', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '93918978-6e7a-4636-9cc7-5da8abcdf459'	System	31 Aug 2020 01:43:03
User entered 'Some interference with activity (2)'	System	31 Aug 2020 01:43:03

**US3362222**

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

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-30T20:42:47', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '93918978-6e7a-4636-9cc7-5da8abcdf459'	System	31 Aug 2020 01:43:03
User entered 'Some interference with activity (2)'	System	31 Aug 2020 01:43:03

**US3362222**

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

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-30T20:42:51', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '93918978-6e7a-4636-9cc7-5da8abcdf459'	System	31 Aug 2020 01:43:03
User entered 'None (0)'	System	31 Aug 2020 01:43:03

**US3362222**

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

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-30T20:42:53', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '93918978-6e7a-4636-9cc7-5da8abcdf459'	System	31 Aug 2020 01:43:03
User entered 'None (0)'	System	31 Aug 2020 01:43:03

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-30T20:42:57', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '93918978-6e7a-4636-9cc7-5da8abcdf459'	System	31 Aug 2020 01:43:03
User entered 'No (N)'	System	31 Aug 2020 01:43:03

**US3362222**

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

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-30T20:43:00', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '93918978-6e7a-4636-9cc7-5da8abcdf459'	System	31 Aug 2020 01:43:03
User entered '30 Aug 2020 20:43'	System	31 Aug 2020 01:43:03

**US3362222**

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

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 21:59:12

**US3362222**

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

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 21:59:12



**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered 'Day 4'	System	28 Aug 2020 21:59:12

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-31T23:25:08', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'c5b281bb-c56d-4446-8b6e-50ec250d5c3c'	System	01 Sep 2020 04:25:52
User entered 'None (0)'	System	01 Sep 2020 04:25:52

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-31T23:25:15', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'c5b281bb-c56d-4446-8b6e-50ec250d5c3c'	System	01 Sep 2020 04:25:52
User entered 'No interference with activity (1)'	System	01 Sep 2020 04:25:52

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-31T23:25:23', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'c5b281bb-c56d-4446-8b6e-50ec250d5c3c'	System	01 Sep 2020 04:25:52
User entered 'No interference with activity (1)'	System	01 Sep 2020 04:25:52

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:59:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-31T23:25:28', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'c5b281bb-c56d-4446-8b6e-50ec250d5c3c'	System	01 Sep 2020 04:25:52
User entered 'No interference with activity (1)'	System	01 Sep 2020 04:25:52

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-31T23:25:40', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'c5b281bb-c56d-4446-8b6e-50ec250d5c3c'	System	01 Sep 2020 04:25:52
User entered 'None (0)'	System	01 Sep 2020 04:25:52

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-31T23:25:43', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'c5b281bb-c56d-4446-8b6e-50ec250d5c3c'	System	01 Sep 2020 04:25:52
User entered 'None (0)'	System	01 Sep 2020 04:25:52

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-31T23:25:47', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'c5b281bb-c56d-4446-8b6e-50ec250d5c3c'	System	01 Sep 2020 04:25:52
User entered 'No (N)'	System	01 Sep 2020 04:25:52



**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-08-31T23:25:50', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'c5b281bb-c56d-4446-8b6e-50ec250d5c3c'	System	01 Sep 2020 04:25:52
User entered '31 Aug 2020 23:25'	System	01 Sep 2020 04:25:52

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 21:59:12

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 21:59:12

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered 'Day 5'	System	28 Aug 2020 21:59:12

**US3362222**

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

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-02T02:37:36', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '9c4ed4a3-a392-48f2-bf36-de344f0cf644'	System	02 Sep 2020 07:38:02
User entered 'None (0)'	System	02 Sep 2020 07:38:02

**US3362222**

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

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-02T02:37:39', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '9c4ed4a3-a392-48f2-bf36-de344f0cf644'	System	02 Sep 2020 07:38:02
User entered 'None (0)'	System	02 Sep 2020 07:38:02

**US3362222**

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

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-02T02:37:46', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '9c4ed4a3-a392-48f2-bf36-de344f0cf644'	System	02 Sep 2020 07:38:02
User entered 'None (0)'	System	02 Sep 2020 07:38:02

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:59:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-02T02:37:48', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '9c4ed4a3-a392-48f2-bf36-de344f0cf644'	System	02 Sep 2020 07:38:02
User entered 'None (0)'	System	02 Sep 2020 07:38:02



**US3362222**

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

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-02T02:37:52', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '9c4ed4a3-a392-48f2-bf36-de344f0cf644'	System	02 Sep 2020 07:38:02
User entered 'None (0)'	System	02 Sep 2020 07:38:02

**US3362222**

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

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-02T02:37:54', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '9c4ed4a3-a392-48f2-bf36-de344f0cf644'	System	02 Sep 2020 07:38:02
User entered 'None (0)'	System	02 Sep 2020 07:38:02

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-02T02:37:57', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '9c4ed4a3-a392-48f2-bf36-de344f0cf644'	System	02 Sep 2020 07:38:02
User entered 'No (N)'	System	02 Sep 2020 07:38:02

**US3362222**

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

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-02T02:38:00', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '9c4ed4a3-a392-48f2-bf36-de344f0cf644'	System	02 Sep 2020 07:38:02
User entered '02 Sep 2020 02:38'	System	02 Sep 2020 07:38:02

**US3362222**

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

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 21:59:12

**US3362222**

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

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 21:59:12

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered 'Day 6'	System	28 Aug 2020 21:59:12

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T02:00:21', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'c067796c-bd7c-4950-99fa-2389ee413868'	System	03 Sep 2020 07:00:41
User entered 'None (0)'	System	03 Sep 2020 07:00:41



**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T02:00:24', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'c067796c-bd7c-4950-99fa-2389ee413868'	System	03 Sep 2020 07:00:41
User entered 'None (0)'	System	03 Sep 2020 07:00:41

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:59:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T02:00:27', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'c067796c-bd7c-4950-99fa-2389ee413868'	System	03 Sep 2020 07:00:41
User entered 'None (0)'	System	03 Sep 2020 07:00:41

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:59:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T02:00:29', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'c067796c-bd7c-4950-99fa-2389ee413868'	System	03 Sep 2020 07:00:41
User entered 'None (0)'	System	03 Sep 2020 07:00:41

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T02:00:32', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'c067796c-bd7c-4950-99fa-2389ee413868'	System	03 Sep 2020 07:00:41
User entered 'None (0)'	System	03 Sep 2020 07:00:41

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T02:00:34', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'c067796c-bd7c-4950-99fa-2389ee413868'	System	03 Sep 2020 07:00:41
User entered 'None (0)'	System	03 Sep 2020 07:00:41

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T02:00:37', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'c067796c-bd7c-4950-99fa-2389ee413868'	System	03 Sep 2020 07:00:41
User entered 'No (N)'	System	03 Sep 2020 07:00:41

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T02:00:40', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'c067796c-bd7c-4950-99fa-2389ee413868'	System	03 Sep 2020 07:00:41
User entered '03 Sep 2020 02:00'	System	03 Sep 2020 07:00:41

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 21:59:12



**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 21:59:12

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered 'Day 7'	System	28 Aug 2020 21:59:12

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T23:45:47', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '71645723-1414-4748-8580-053d88ec6cf6'	System	04 Sep 2020 04:46:07
User entered 'None (0)'	System	04 Sep 2020 04:46:07

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T23:45:49', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '71645723-1414-4748-8580-053d88ec6cf6'	System	04 Sep 2020 04:46:07
User entered 'None (0)'	System	04 Sep 2020 04:46:07

US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:59:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T23:45:50', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '71645723-1414-4748-8580-053d88ec6cf6'	System	04 Sep 2020 04:46:07
User entered 'None (0)'	System	04 Sep 2020 04:46:07

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T23:45:52', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '71645723-1414-4748-8580-053d88ec6cf6'	System	04 Sep 2020 04:46:07
User entered 'None (0)'	System	04 Sep 2020 04:46:07

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T23:45:54', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '71645723-1414-4748-8580-053d88ec6cf6'	System	04 Sep 2020 04:46:07
User entered 'None (0)'	System	04 Sep 2020 04:46:07

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T23:45:56', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '71645723-1414-4748-8580-053d88ec6cf6'	System	04 Sep 2020 04:46:07
User entered 'None (0)'	System	04 Sep 2020 04:46:07



US3362222

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T23:45:59', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '71645723-1414-4748-8580-053d88ec6cf6'	System	04 Sep 2020 04:46:07
User entered 'No (N)'	System	04 Sep 2020 04:46:07

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-09-03T23:46:03', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '71645723-1414-4748-8580-053d88ec6cf6'	System	04 Sep 2020 04:46:07
User entered '03 Sep 2020 23:46'	System	04 Sep 2020 04:46:07

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 21:59:12

**US3362222**

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

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 21:59:12

US3362222

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 16:44:05

US3362222

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Sep 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 22:00:14
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 16:44:05

US3362222

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Sep 2020 16:44:05

US3362222

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:44:05



US3362222

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 16:44:09

**US3362222**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:59:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Sep 2020 16:44:09

US3362222

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:44:51

US3362222

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 16:44:51

US3362222

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Sep 2020 16:44:51

**US3362222**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:44:51

US3362222

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:44:58

**US3362222**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:59:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Sep 2020 16:44:58



US3362222

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 14:09:12

US3362222

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 14:09:12

US3362222

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Sep 2020 14:09:12

**US3362222**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 14:09:12

US3362222

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 14:09:20

**US3362222**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:59:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Sep 2020 14:09:20

US3362222

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 14:43:34

US3362222

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered '02 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 14:43:34



US3362222

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	02 Oct 2020 14:43:34

**US3362222**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:59:15**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	02 Oct 2020 14:43:34

US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	02 Oct 2020 19:30:59

US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 19:30:59

US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 19:30:59

US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered '08:15'	(b) (4), (b) (6)	02 Oct 2020 19:30:59

**US3362222**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered '2 Oct 2020 08:15'	System	02 Oct 2020 19:30:59

US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37' C	(b) (4), (b) (6)	02 Oct 2020 19:30:59



US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	02 Oct 2020 19:30:59

US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 19:30:59

US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '78'	(b) (4), (b) (6)	02 Oct 2020 19:30:59

US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Oct 2020 19:30:59

US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered '18'	(b) (4), (b) (6)	02 Oct 2020 19:30:59

US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Oct 2020 19:30:59

US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '136'	(b) (4), (b) (6)	02 Oct 2020 19:30:59

US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 19:30:59



US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '84'	(b) (4), (b) (6)	02 Oct 2020 19:30:59

US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 19:30:59

US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	02 Oct 2020 19:30:59

US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 19:30:59

US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 19:30:59

US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered '10:05'	(b) (4), (b) (6)	02 Oct 2020 19:30:59

**US3362222**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered '2 Oct 2020 10:05'	System	02 Oct 2020 19:30:59

US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.7' C	(b) (4), (b) (6)	02 Oct 2020 19:30:59



US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	02 Oct 2020 19:30:59

US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 19:30:59

US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '61'	(b) (4), (b) (6)	02 Oct 2020 19:30:59

**US3362222**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:59:15**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Oct 2020 19:30:59

US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered '18'	(b) (4), (b) (6)	02 Oct 2020 19:30:59

US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Oct 2020 19:30:59

US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '132'	(b) (4), (b) (6)	02 Oct 2020 19:30:59

US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 19:30:59



US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '90'	(b) (4), (b) (6)	02 Oct 2020 19:30:59

US3362222

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 19:30:59

US3362222

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:15

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 14:43:44

US3362222

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 14:43:44

US3362222

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:59:15

Was the pregnancy test performed?

Audit	User	Time (GMT)
User closed query 'Per CDM: Subject is with non-childbearing potential, however pregnancy test was performed. Please clarify why pregnancy test was performed. Thank you! ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 14:40:20
Query 'Per CDM: Subject is with non-childbearing potential, however pregnancy test was performed. Please clarify why pregnancy test was performed. Thank you! ' answered with 'per contraception section of protocol, she is childbearing potential, epip was sent to clarify ' (Site from DM).	Crystal Rowell (b) (4) (b) (4)	23 Oct 2020 19:41:56
User opened query 'Per CDM: Subject is with non-childbearing potential, however pregnancy test was performed. Please clarify why pregnancy test was performed. Thank you! ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 11:41:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 14:44:37

US3362222

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:59:15

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 14:44:37

US3362222

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:59:15

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	(b) (4), (b) (6)	02 Oct 2020 14:44:37

US3362222

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:59:15

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	02 Oct 2020 14:44:37



US3362222

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:59:15

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 14:44:37

US3362222

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:59:15

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 14:44:37

US3362222

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:59:15

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 14:44:37

**US3362222**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 14:44:37

US3362222

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 14:45:10

US3362222

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:15

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 14:45:10

US3362222

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:15

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)	02 Oct 2020 14:45:10

US3362222

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:15

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	02 Oct 2020 14:45:10



US3362222

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '02 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 14:45:10

US3362222

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered '09:29'	(b) (4), (b) (6)	02 Oct 2020 14:45:10

**US3362222**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered '02 Oct 2020 09:29'	System	02 Oct 2020 14:45:10

US3362222

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:15

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	02 Oct 2020 14:45:10

US3362222

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	02 Oct 2020 14:45:10

US3362222

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	02 Oct 2020 14:45:10

US3362222

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 14:45:34

US3362222

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 14:45:34



US3362222

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '09:00'	(b) (4), (b) (6)	02 Oct 2020 14:45:34

US3362222

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered '02 Oct 2020 09:00'	System	02 Oct 2020 14:45:34

US3362222

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:59:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 14:45:53

US3362222

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:15

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	02 Oct 2020 14:45:53

US3362222

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 14:45:53

US3362222

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '09:03'	(b) (4), (b) (6)	02 Oct 2020 14:45:53

**US3362222**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered '02 Oct 2020 09:03'	System	02 Oct 2020 14:45:53

US3362222

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:15

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	02 Oct 2020 14:45:53



US3362222

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 14:45:53

US3362222

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 14:45:53

**US3362222**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:59:15**

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 14:45:53

US3362222

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 14:45:59

**US3362222**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:59:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 14:45:59

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 14:45:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 14:45:10

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T10:09:54', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '1d883b59-d2a6-4670-a14d-c4592e42532d'	System	02 Oct 2020 15:10:14
User entered 'Yes (Y)'	System	02 Oct 2020 15:10:14

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T10:10:01', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '1d883b59-d2a6-4670-a14d-c4592e42532d'	System	02 Oct 2020 15:10:14
User entered '98.0'	System	02 Oct 2020 15:10:14



US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T10:10:05', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '1d883b59-d2a6-4670-a14d-c4592e42532d'	System	02 Oct 2020 15:10:14
User entered 'No (N)'	System	02 Oct 2020 15:10:14

**US3362222**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T10:10:12', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '1d883b59-d2a6-4670-a14d-c4592e42532d'	System	02 Oct 2020 15:10:14
User entered '02 Oct 2020 10:10'	System	02 Oct 2020 15:10:14

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 09:49'	System	02 Oct 2020 14:45:10

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:19'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 14:45:10
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 14:45:10

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T21:11:12', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'bc319917-cdd0-49e5-8e3c-9d754ff61cc0'	System	03 Oct 2020 02:14:57
User entered 'Yes (Y)'	System	03 Oct 2020 02:14:57

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T21:14:38', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'bc319917-cdd0-49e5-8e3c-9d754ff61cc0'	System	03 Oct 2020 02:14:57
User entered '98.7'	System	03 Oct 2020 02:14:57

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T21:14:42', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'bc319917-cdd0-49e5-8e3c-9d754ff61cc0'	System	03 Oct 2020 02:14:57
User entered 'Yes (Y)'	System	03 Oct 2020 02:14:57



US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T21:14:51', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'bc319917-cdd0-49e5-8e3c-9d754ff61cc0'	System	03 Oct 2020 02:14:57
User entered '0'	System	03 Oct 2020 02:14:57

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'tylenol captured on conmed log' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 20:06:56
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T21:14:51', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'bc319917-cdd0-49e5-8e3c-9d754ff61cc0'	System	03 Oct 2020 02:14:57
User entered '1'	System	03 Oct 2020 02:14:57

**US3362222**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T21:14:55', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'bc319917-cdd0-49e5-8e3c-9d754ff61cc0'	System	03 Oct 2020 02:14:57
User entered '02 Oct 2020 21:14'	System	03 Oct 2020 02:14:57

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 13:14'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 14:45:10
User entered 'Day 2'	System	02 Oct 2020 14:45:10

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:59:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-03T22:48:30', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '64ce0c69-39d5-4d77-b4a6-4b4b9cd5635d'	System	04 Oct 2020 03:49:05
User entered 'Yes (Y)'	System	04 Oct 2020 03:49:05

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:59:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-03T22:48:35', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '64ce0c69-39d5-4d77-b4a6-4b4b9cd5635d' User entered '98.1'	System	04 Oct 2020 03:49:05



US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-03T22:48:39', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '64ce0c69-39d5-4d77-b4a6-4b4b9cd5635d'	System	04 Oct 2020 03:49:05
User entered 'Yes (Y)'	System	04 Oct 2020 03:49:05

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'tylenol captured on conmed log' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 20:07:06
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-03T22:48:58', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '64ce0c69-39d5-4d77-b4a6-4b4b9cd5635d'	System	04 Oct 2020 03:49:05
User entered '1'	System	04 Oct 2020 03:49:05

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:59:15

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-03T22:48:58', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '64ce0c69-39d5-4d77-b4a6-4b4b9cd5635d' User entered '0'	System	04 Oct 2020 03:49:05

**US3362222**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-03T22:49:03', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '64ce0c69-39d5-4d77-b4a6-4b4b9cd5635d'	System	04 Oct 2020 03:49:05
User entered '03 Oct 2020 22:49'	System	04 Oct 2020 03:49:05

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:59:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 14:45:10

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:59:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 14:45:10
User entered 'Day 3'	System	02 Oct 2020 14:45:10

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-04T22:52:40', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '52d82ec6-95e9-4e34-9a98-5c5ea196a6ba' User entered 'Yes (Y)'	System	05 Oct 2020 03:53:03



US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-04T22:52:49', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '52d82ec6-95e9-4e34-9a98-5c5ea196a6ba' User entered '98.1'	System	05 Oct 2020 03:53:03

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-04T22:52:53', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '52d82ec6-95e9-4e34-9a98-5c5ea196a6ba' User entered 'Yes (Y)'	System	05 Oct 2020 03:53:03

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-04T22:52:58', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '52d82ec6-95e9-4e34-9a98-5c5ea196a6ba' User entered '0'	System	05 Oct 2020 03:53:03

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:15

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'tylenol captured on conmed log' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 20:07:12
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-04T22:52:58', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '52d82ec6-95e9-4e34-9a98-5c5ea196a6ba' User entered '1'	System	05 Oct 2020 03:53:03
	System	05 Oct 2020 03:53:03
	System	05 Oct 2020 03:53:03

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-04T22:53:00', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '52d82ec6-95e9-4e34-9a98-5c5ea196a6ba' User entered '04 Oct 2020 22:53'	System	05 Oct 2020 03:53:03
	System	05 Oct 2020 03:53:03

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 14:45:10

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 14:45:10

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 14:45:10
User entered 'Day 4'	System	02 Oct 2020 14:45:10



US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:59:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-05T22:54:50', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '90dcfda7-6936-4dcf-8e30-40c842cfc6b1'	System	06 Oct 2020 03:55:06
User entered 'Yes (Y)'	System	06 Oct 2020 03:55:06

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:59:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-05T22:54:56', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '90dcfda7-6936-4dcf-8e30-40c842cfc6b1' User entered '98.6'	System	06 Oct 2020 03:55:06

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-05T22:55:00', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '90dcfda7-6936-4dcf-8e30-40c842cfc6b1'	System	06 Oct 2020 03:55:06
User entered 'No (N)'	System	06 Oct 2020 03:55:06

**US3362222**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-05T22:55:03', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '90dcfda7-6936-4dcf-8e30-40c842cfc6b1'	System	06 Oct 2020 03:55:06
User entered '05 Oct 2020 22:55'	System	06 Oct 2020 03:55:06

**US3362222**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 14:45:10

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:59:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 14:45:10

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 14:45:10
User entered 'Day 5'	System	02 Oct 2020 14:45:10

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:59:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-06T23:08:11', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '5a8054ea-3915-413e-8269-f0f3db27070f'	System	07 Oct 2020 04:08:26
User entered 'Yes (Y)'	System	07 Oct 2020 04:08:26



US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:59:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-06T23:08:16', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '5a8054ea-3915-413e-8269-f0f3db27070f'	System	07 Oct 2020 04:08:26
User entered '98.4'	System	07 Oct 2020 04:08:26

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-06T23:08:19', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '5a8054ea-3915-413e-8269-f0f3db27070f'	System	07 Oct 2020 04:08:26
User entered 'No (N)'	System	07 Oct 2020 04:08:26

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-06T23:08:21', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '5a8054ea-3915-413e-8269-f0f3db27070f' User entered '06 Oct 2020 23:08'	System	07 Oct 2020 04:08:26
	System	07 Oct 2020 04:08:26

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:59:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 14:45:10
User entered 'Day 6'	System	02 Oct 2020 14:45:10

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:59:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-07T22:30:07', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '934ba408-68a1-4cd1-bf7c-80743b2b626f' User entered 'Yes (Y)'	System	08 Oct 2020 03:30:21

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:59:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-07T22:30:12', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '934ba408-68a1-4cd1-bf7c-80743b2b626f' User entered '97.5'	System	08 Oct 2020 03:30:21



US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-07T22:30:15', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '934ba408-68a1-4cd1-bf7c-80743b2b626f' User entered 'No (N)'	System	08 Oct 2020 03:30:21

**US3362222**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-07T22:30:17', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '934ba408-68a1-4cd1-bf7c-80743b2b626f' User entered '07 Oct 2020 22:30'	System	08 Oct 2020 03:30:21
	System	08 Oct 2020 03:30:21

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:59:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 14:45:10

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 14:45:10
User entered 'Day 7'	System	02 Oct 2020 14:45:10

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:59:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-08T22:28:44', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '0daf4b7b-c29f-4730-be2f-0507bd5b9580'	System	09 Oct 2020 03:29:03
User entered 'Yes (Y)'	System	09 Oct 2020 03:29:03

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:59:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-08T22:28:53', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '0daf4b7b-c29f-4730-be2f-0507bd5b9580'	System	09 Oct 2020 03:29:03
User entered '97.1'	System	09 Oct 2020 03:29:03

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-08T22:28:56', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '0daf4b7b-c29f-4730-be2f-0507bd5b9580'	System	09 Oct 2020 03:29:03
User entered 'No (N)'	System	09 Oct 2020 03:29:03



**US3362222**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-08T22:28:59', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '0daf4b7b-c29f-4730-be2f-0507bd5b9580'	System	09 Oct 2020 03:29:03
User entered '08 Oct 2020 22:28'	System	09 Oct 2020 03:29:03

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:59:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 14:45:10

US3362222

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:59:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 14:45:10

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 14:45:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 14:45:10

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T10:10:36', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'dfd6c034-9def-463d-babc-42ebe9ce4769'	System	02 Oct 2020 15:11:39
User entered 'None (1)'	System	02 Oct 2020 15:11:39

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T10:11:12', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'dfd6c034-9def-463d-babc-42ebe9ce4769'	System	02 Oct 2020 15:11:39
User entered 'No (N)'	System	02 Oct 2020 15:11:39

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T10:11:26', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'dfd6c034-9def-463d-babc-42ebe9ce4769'	System	02 Oct 2020 15:11:39
User entered 'No (N)'	System	02 Oct 2020 15:11:39

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T10:11:30', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'dfd6c034-9def-463d-babc-42ebe9ce4769'	System	02 Oct 2020 15:11:39
User entered 'None (1)'	System	02 Oct 2020 15:11:39



**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T10:11:34', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'dfd6c034-9def-463d-babc-42ebe9ce4769'	System	02 Oct 2020 15:11:39
User entered '02 Oct 2020 10:11'	System	02 Oct 2020 15:11:39

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 09:49'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:19'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 14:45:10
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 14:45:10

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T21:07:04', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '7aaca4ee-b2c8-4035-a481-6c7c1a73b2f1'	System	03 Oct 2020 02:11:06
User entered 'Does not interfere with activity (2)'	System	03 Oct 2020 02:11:06

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T21:07:38', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '7aaca4ee-b2c8-4035-a481-6c7c1a73b2f1'	System	03 Oct 2020 02:11:06
User entered 'No (N)'	System	03 Oct 2020 02:11:06

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T21:07:43', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '7aaca4ee-b2c8-4035-a481-6c7c1a73b2f1'	System	03 Oct 2020 02:11:06
User entered 'Yes (Y)'	System	03 Oct 2020 02:11:06

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T21:10:48', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '7aaca4ee-b2c8-4035-a481-6c7c1a73b2f1' User entered '7'	System	03 Oct 2020 02:11:06
	System	03 Oct 2020 02:11:06



US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T21:10:58', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '7aaca4ee-b2c8-4035-a481-6c7c1a73b2f1'	System	03 Oct 2020 02:11:06
User entered 'None (1)'	System	03 Oct 2020 02:11:06

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T21:11:02', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '7aaca4ee-b2c8-4035-a481-6c7c1a73b2f1'	System	03 Oct 2020 02:11:06
User entered '02 Oct 2020 21:11'	System	03 Oct 2020 02:11:06

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 13:14'	System	02 Oct 2020 14:45:10

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 14:45:10
User entered 'Day 2'	System	02 Oct 2020 14:45:10

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-03T22:49:17', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '9843614e-3995-4cc3-bffe-1fa0070aea23'	System	04 Oct 2020 03:50:45
User entered 'Does not interfere with activity (2)'	System	04 Oct 2020 03:50:45

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:59:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-03T22:49:20', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '9843614e-3995-4cc3-bffe-1fa0070aea23'	System	04 Oct 2020 03:50:45
User entered 'Yes (Y)'	System	04 Oct 2020 03:50:45

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:59:15

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-03T22:50:19', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '9843614e-3995-4cc3-bffe-1fa0070aea23' User entered '2'	System	04 Oct 2020 03:50:45
	System	04 Oct 2020 03:50:45



US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:59:15

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-03T22:50:24', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '9843614e-3995-4cc3-bffe-1fa0070aea23'	System	04 Oct 2020 03:50:45
User entered 'Yes (Y)'	System	04 Oct 2020 03:50:45

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:59:15

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

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-03T22:50:32', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '9843614e-3995-4cc3-bffe-1fa0070aea23' User entered '2'	System	04 Oct 2020 03:50:45
	System	04 Oct 2020 03:50:45

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-03T22:50:40', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '9843614e-3995-4cc3-bffe-1fa0070aea23'	System	04 Oct 2020 03:50:45
User entered 'None (1)'	System	04 Oct 2020 03:50:45

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-03T22:50:43', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '9843614e-3995-4cc3-bffe-1fa0070aea23'	System	04 Oct 2020 03:50:45
User entered '03 Oct 2020 22:50'	System	04 Oct 2020 03:50:45

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:59:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 14:45:10

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:59:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 14:45:10
User entered 'Day 3'	System	02 Oct 2020 14:45:10

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-04T22:49:52', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'd539b3f5-349a-461d-887c-05220992df95'	System	05 Oct 2020 03:51:21
User entered 'Does not interfere with activity (2)'	System	05 Oct 2020 03:51:21



US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-04T22:50:03', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'd539b3f5-349a-461d-887c-05220992df95'	System	05 Oct 2020 03:51:21
User entered 'No (N)'	System	05 Oct 2020 03:51:21

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-04T22:50:07', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'd539b3f5-349a-461d-887c-05220992df95'	System	05 Oct 2020 03:51:21
User entered 'Yes (Y)'	System	05 Oct 2020 03:51:21

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:15

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-04T22:51:03', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'd539b3f5-349a-461d-887c-05220992df95' User entered '3'	System	05 Oct 2020 03:51:21
	System	05 Oct 2020 03:51:21

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-04T22:51:14', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'd539b3f5-349a-461d-887c-05220992df95'	System	05 Oct 2020 03:51:21
User entered 'None (1)'	System	05 Oct 2020 03:51:21

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-04T22:51:17', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'd539b3f5-349a-461d-887c-05220992df95'	System	05 Oct 2020 03:51:21
User entered '04 Oct 2020 22:51'	System	05 Oct 2020 03:51:21

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 14:45:10

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 14:45:10
User entered 'Day 4'	System	02 Oct 2020 14:45:10



US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-05T22:55:14', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '3234d664-fdc2-4231-af9e-b88e5d4d4565'	System	06 Oct 2020 03:55:28
User entered 'None (1)'	System	06 Oct 2020 03:55:28

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:59:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-05T22:55:17', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '3234d664-fdc2-4231-af9e-b88e5d4d4565'	System	06 Oct 2020 03:55:28
User entered 'No (N)'	System	06 Oct 2020 03:55:28

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:59:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-05T22:55:19', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '3234d664-fdc2-4231-af9e-b88e5d4d4565'	System	06 Oct 2020 03:55:28
User entered 'No (N)'	System	06 Oct 2020 03:55:28

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-05T22:55:22', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '3234d664-fdc2-4231-af9e-b88e5d4d4565'	System	06 Oct 2020 03:55:28
User entered 'None (1)'	System	06 Oct 2020 03:55:28

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-05T22:55:25', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '3234d664-fdc2-4231-af9e-b88e5d4d4565'	System	06 Oct 2020 03:55:28
User entered '05 Oct 2020 22:55'	System	06 Oct 2020 03:55:28

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 14:45:10
User entered 'Day 5'	System	02 Oct 2020 14:45:10



US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-06T22:40:38', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'b1ba74bf-2450-4b19-9452-9076022b8205'	System	07 Oct 2020 03:40:51
User entered 'None (1)'	System	07 Oct 2020 03:40:51

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:59:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-06T22:40:41', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'b1ba74bf-2450-4b19-9452-9076022b8205'	System	07 Oct 2020 03:40:51
User entered 'No (N)'	System	07 Oct 2020 03:40:51

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:59:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-06T22:40:43', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'b1ba74bf-2450-4b19-9452-9076022b8205'	System	07 Oct 2020 03:40:51
User entered 'No (N)'	System	07 Oct 2020 03:40:51

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-06T22:40:46', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'b1ba74bf-2450-4b19-9452-9076022b8205'	System	07 Oct 2020 03:40:51
User entered 'None (1)'	System	07 Oct 2020 03:40:51

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-06T22:40:48', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'b1ba74bf-2450-4b19-9452-9076022b8205'	System	07 Oct 2020 03:40:51
User entered '06 Oct 2020 22:40'	System	07 Oct 2020 03:40:51

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 14:45:10

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:59:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 14:45:10
User entered 'Day 6'	System	02 Oct 2020 14:45:10



US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-07T22:28:20', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'de0803ec-ae6-456a-8b81-bf44146e14fd'	System	08 Oct 2020 03:28:30
User entered 'None (1)'	System	08 Oct 2020 03:28:30

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:59:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-07T22:28:19', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'de0803ec-ae6-456a-8b81-bf44146e14fd'	System	08 Oct 2020 03:28:30
User entered 'No (N)'	System	08 Oct 2020 03:28:30

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:59:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-07T22:28:22', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'de0803ec-ae6-456a-8b81-bf44146e14fd'	System	08 Oct 2020 03:28:30
User entered 'No (N)'	System	08 Oct 2020 03:28:30

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-07T22:28:24', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'de0803ec-ae6-456a-8b81-bf44146e14fd'	System	08 Oct 2020 03:28:30
User entered 'None (1)'	System	08 Oct 2020 03:28:30

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-07T22:28:28', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'de0803ec-ae6-456a-8b81-bf44146e14fd'	System	08 Oct 2020 03:28:30
User entered '07 Oct 2020 22:28'	System	08 Oct 2020 03:28:30

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 14:45:10
User entered 'Day 7'	System	02 Oct 2020 14:45:10



US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-08T18:57:42', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '1131d825-b03c-4aac-878c-b22bcaacad4e'	System	08 Oct 2020 23:57:55
User entered 'None (1)'	System	08 Oct 2020 23:57:55

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:59:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-08T18:57:44', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '1131d825-b03c-4aac-878c-b22bcaacad4e'	System	08 Oct 2020 23:57:55
User entered 'No (N)'	System	08 Oct 2020 23:57:55

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:59:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-08T18:57:46', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '1131d825-b03c-4aac-878c-b22bcaacad4e'	System	08 Oct 2020 23:57:55
User entered 'No (N)'	System	08 Oct 2020 23:57:55

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-08T18:57:48', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '1131d825-b03c-4aac-878c-b22bcaacad4e'	System	08 Oct 2020 23:57:55
User entered 'None (1)'	System	08 Oct 2020 23:57:55

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-08T18:57:50', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '1131d825-b03c-4aac-878c-b22bcaacad4e'	System	08 Oct 2020 23:57:55
User entered '08 Oct 2020 18:57'	System	08 Oct 2020 23:57:55

US3362222

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:59:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 14:45:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 14:45:10



**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:15**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T10:12:01', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'ba5eb059-04de-4683-956c-faf3cf019a25'	System	02 Oct 2020 15:12:56
User entered 'None (0)'	System	02 Oct 2020 15:12:56

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:15**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T10:12:06', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'ba5eb059-04de-4683-956c-faf3cf019a25'	System	02 Oct 2020 15:12:56
User entered 'None (0)'	System	02 Oct 2020 15:12:56

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:15**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T10:12:18', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'ba5eb059-04de-4683-956c-faf3cf019a25'	System	02 Oct 2020 15:12:56
User entered 'None (0)'	System	02 Oct 2020 15:12:56

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T10:12:21', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'ba5eb059-04de-4683-956c-faf3cf019a25'	System	02 Oct 2020 15:12:56
User entered 'None (0)'	System	02 Oct 2020 15:12:56

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:15**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T10:12:24', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'ba5eb059-04de-4683-956c-faf3cf019a25'	System	02 Oct 2020 15:12:56
User entered 'None (0)'	System	02 Oct 2020 15:12:56

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:15**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T10:12:43', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'ba5eb059-04de-4683-956c-faf3cf019a25'	System	02 Oct 2020 15:12:56
User entered 'None (0)'	System	02 Oct 2020 15:12:56

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T10:12:50', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'ba5eb059-04de-4683-956c-faf3cf019a25'	System	02 Oct 2020 15:12:56
User entered 'No (N)'	System	02 Oct 2020 15:12:56

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T10:12:52', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'ba5eb059-04de-4683-956c-faf3cf019a25'	System	02 Oct 2020 15:12:56
User entered '02 Oct 2020 10:12'	System	02 Oct 2020 15:12:56



US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:59:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 09:49'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:19'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 14:45:10
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:15**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T21:15:15', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '16b9f8df-c0f7-47b3-9768-7b3dc5f399b6'	System	03 Oct 2020 02:15:41
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	03 Oct 2020 02:15:41

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:15**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T21:15:19', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '16b9f8df-c0f7-47b3-9768-7b3dc5f399b6'	System	03 Oct 2020 02:15:41
User entered 'No interference with activity (1)'	System	03 Oct 2020 02:15:41

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:15**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T21:15:25', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '16b9f8df-c0f7-47b3-9768-7b3dc5f399b6'	System	03 Oct 2020 02:15:41
User entered 'None (0)'	System	03 Oct 2020 02:15:41

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T21:15:28', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '16b9f8df-c0f7-47b3-9768-7b3dc5f399b6'	System	03 Oct 2020 02:15:41
User entered 'None (0)'	System	03 Oct 2020 02:15:41

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:15**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T21:15:31', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '16b9f8df-c0f7-47b3-9768-7b3dc5f399b6'	System	03 Oct 2020 02:15:41
User entered 'None (0)'	System	03 Oct 2020 02:15:41



**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:15**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T21:15:33', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '16b9f8df-c0f7-47b3-9768-7b3dc5f399b6'	System	03 Oct 2020 02:15:41
User entered 'None (0)'	System	03 Oct 2020 02:15:41

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T21:15:36', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '16b9f8df-c0f7-47b3-9768-7b3dc5f399b6'	System	03 Oct 2020 02:15:41
User entered 'No (N)'	System	03 Oct 2020 02:15:41

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-02T21:15:39', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '16b9f8df-c0f7-47b3-9768-7b3dc5f399b6'	System	03 Oct 2020 02:15:41
User entered '02 Oct 2020 21:15'	System	03 Oct 2020 02:15:41

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:59:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 13:14'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 14:45:10
User entered 'Day 2'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:15**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-03T22:50:53', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '2ed37283-2e41-4fcf-91cc-a13cd8e6e696'	System	04 Oct 2020 03:51:33
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	04 Oct 2020 03:51:33

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:15**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-03T22:50:57', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '2ed37283-2e41-4fcf-91cc-a13cd8e6e696'	System	04 Oct 2020 03:51:33
User entered 'No interference with activity (1)'	System	04 Oct 2020 03:51:33



**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:15**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-03T22:51:08', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '2ed37283-2e41-4fcf-91cc-a13cd8e6e696'	System	04 Oct 2020 03:51:33
User entered 'None (0)'	System	04 Oct 2020 03:51:33

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:15**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-03T22:51:15', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '2ed37283-2e41-4fcf-91cc-a13cd8e6e696'	System	04 Oct 2020 03:51:33
User entered 'No interference with activity (1)'	System	04 Oct 2020 03:51:33

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:15**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-03T22:51:17', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '2ed37283-2e41-4fcf-91cc-a13cd8e6e696'	System	04 Oct 2020 03:51:33
User entered 'None (0)'	System	04 Oct 2020 03:51:33

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:15**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-03T22:51:20', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '2ed37283-2e41-4fcf-91cc-a13cd8e6e696'	System	04 Oct 2020 03:51:33
User entered 'None (0)'	System	04 Oct 2020 03:51:33

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-03T22:51:26', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '2ed37283-2e41-4fcf-91cc-a13cd8e6e696'	System	04 Oct 2020 03:51:33
User entered 'No (N)'	System	04 Oct 2020 03:51:33

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-03T22:51:29', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '2ed37283-2e41-4fcf-91cc-a13cd8e6e696'	System	04 Oct 2020 03:51:33
User entered '03 Oct 2020 22:51'	System	04 Oct 2020 03:51:33

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 14:45:10



**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 14:45:10
User entered 'Day 3'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-04T22:51:26', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '8c670baa-2a4c-4523-aa02-4e94f21a726d'	System	05 Oct 2020 03:51:53
User entered 'No interference with activity (1)'	System	05 Oct 2020 03:51:53

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-04T22:51:32', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '8c670baa-2a4c-4523-aa02-4e94f21a726d'	System	05 Oct 2020 03:51:53
User entered 'No interference with activity (1)'	System	05 Oct 2020 03:51:53

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-04T22:51:37', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '8c670baa-2a4c-4523-aa02-4e94f21a726d'	System	05 Oct 2020 03:51:53
User entered 'No interference with activity (1)'	System	05 Oct 2020 03:51:53

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-04T22:51:40', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '8c670baa-2a4c-4523-aa02-4e94f21a726d'	System	05 Oct 2020 03:51:53
User entered 'No interference with activity (1)'	System	05 Oct 2020 03:51:53

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-04T22:51:42', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '8c670baa-2a4c-4523-aa02-4e94f21a726d'	System	05 Oct 2020 03:51:53
User entered 'None (0)'	System	05 Oct 2020 03:51:53

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-04T22:51:45', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '8c670baa-2a4c-4523-aa02-4e94f21a726d'	System	05 Oct 2020 03:51:53
User entered 'None (0)'	System	05 Oct 2020 03:51:53

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-04T22:51:48', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '8c670baa-2a4c-4523-aa02-4e94f21a726d'	System	05 Oct 2020 03:51:53
User entered 'No (N)'	System	05 Oct 2020 03:51:53



**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-04T22:51:52', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '8c670baa-2a4c-4523-aa02-4e94f21a726d'	System	05 Oct 2020 03:51:53
User entered '04 Oct 2020 22:51'	System	05 Oct 2020 03:51:53

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 14:45:10
User entered 'Day 4'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:15**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-05T22:55:31', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'ff3a99fc-2512-4bc4-8ff6-d03e8c781eef'	System	06 Oct 2020 03:55:50
User entered 'None (0)'	System	06 Oct 2020 03:55:50

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:15**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-05T22:55:34', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'ff3a99fc-2512-4bc4-8ff6-d03e8c781eef'	System	06 Oct 2020 03:55:50
User entered 'None (0)'	System	06 Oct 2020 03:55:50

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:59:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-05T22:55:37', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'ff3a99fc-2512-4bc4-8ff6-d03e8c781eef'	System	06 Oct 2020 03:55:50
User entered 'None (0)'	System	06 Oct 2020 03:55:50

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:59:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-05T22:55:39', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'ff3a99fc-2512-4bc4-8ff6-d03e8c781eef'	System	06 Oct 2020 03:55:50
User entered 'None (0)'	System	06 Oct 2020 03:55:50



**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:15**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-05T22:55:42', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'ff3a99fc-2512-4bc4-8ff6-d03e8c781eef'	System	06 Oct 2020 03:55:50
User entered 'None (0)'	System	06 Oct 2020 03:55:50

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:15**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-05T22:55:44', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'ff3a99fc-2512-4bc4-8ff6-d03e8c781eef'	System	06 Oct 2020 03:55:50
User entered 'None (0)'	System	06 Oct 2020 03:55:50

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-05T22:55:46', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'ff3a99fc-2512-4bc4-8ff6-d03e8c781eef'	System	06 Oct 2020 03:55:50
User entered 'No (N)'	System	06 Oct 2020 03:55:50

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-05T22:55:49', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'ff3a99fc-2512-4bc4-8ff6-d03e8c781eef'	System	06 Oct 2020 03:55:50
User entered '05 Oct 2020 22:55'	System	06 Oct 2020 03:55:50

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 14:45:10

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:59:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 14:45:10
User entered 'Day 5'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-06T22:40:54', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '92164a16-8e81-4bae-bec4-4cc91160f067'	System	07 Oct 2020 03:41:15
User entered 'None (0)'	System	07 Oct 2020 03:41:15



**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-06T22:40:57', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '92164a16-8e81-4bae-bec4-4cc91160f067'	System	07 Oct 2020 03:41:15
User entered 'None (0)'	System	07 Oct 2020 03:41:15

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-06T22:41:00', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '92164a16-8e81-4bae-bec4-4cc91160f067'	System	07 Oct 2020 03:41:15
User entered 'None (0)'	System	07 Oct 2020 03:41:15

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-06T22:41:03', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '92164a16-8e81-4bae-bec4-4cc91160f067'	System	07 Oct 2020 03:41:15
User entered 'None (0)'	System	07 Oct 2020 03:41:15

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-06T22:41:06', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '92164a16-8e81-4bae-bec4-4cc91160f067'	System	07 Oct 2020 03:41:15
User entered 'None (0)'	System	07 Oct 2020 03:41:15

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-06T22:41:08', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '92164a16-8e81-4bae-bec4-4cc91160f067'	System	07 Oct 2020 03:41:15
User entered 'None (0)'	System	07 Oct 2020 03:41:15

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-06T22:41:11', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '92164a16-8e81-4bae-bec4-4cc91160f067'	System	07 Oct 2020 03:41:15
User entered 'No (N)'	System	07 Oct 2020 03:41:15

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-06T22:41:13', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '92164a16-8e81-4bae-bec4-4cc91160f067'	System	07 Oct 2020 03:41:15
User entered '06 Oct 2020 22:41'	System	07 Oct 2020 03:41:15

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 14:45:10



**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 14:45:10
User entered 'Day 6'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:15**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-07T22:28:32', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'dd8b4715-603b-4073-8d7d-f7a4034740ad'	System	08 Oct 2020 03:28:51
User entered 'None (0)'	System	08 Oct 2020 03:28:51

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:15**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-07T22:28:34', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'dd8b4715-603b-4073-8d7d-f7a4034740ad'	System	08 Oct 2020 03:28:51
User entered 'None (0)'	System	08 Oct 2020 03:28:51

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:59:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-07T22:28:36', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'dd8b4715-603b-4073-8d7d-f7a4034740ad'	System	08 Oct 2020 03:28:51
User entered 'None (0)'	System	08 Oct 2020 03:28:51

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:59:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-07T22:28:38', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'dd8b4715-603b-4073-8d7d-f7a4034740ad'	System	08 Oct 2020 03:28:51
User entered 'None (0)'	System	08 Oct 2020 03:28:51

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:15**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-07T22:28:41', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'dd8b4715-603b-4073-8d7d-f7a4034740ad'	System	08 Oct 2020 03:28:51
User entered 'None (0)'	System	08 Oct 2020 03:28:51

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:15**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-07T22:28:43', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'dd8b4715-603b-4073-8d7d-f7a4034740ad'	System	08 Oct 2020 03:28:51
User entered 'None (0)'	System	08 Oct 2020 03:28:51



US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-07T22:28:46', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'dd8b4715-603b-4073-8d7d-f7a4034740ad'	System	08 Oct 2020 03:28:51
User entered 'No (N)'	System	08 Oct 2020 03:28:51

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-07T22:28:48', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'dd8b4715-603b-4073-8d7d-f7a4034740ad'	System	08 Oct 2020 03:28:51
User entered '07 Oct 2020 22:28'	System	08 Oct 2020 03:28:51

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 14:45:10
User entered 'Day 7'	System	02 Oct 2020 14:45:10

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:15**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-08T18:57:54', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'a8f13fa9-725a-4b4d-a144-b656253e3f5b'	System	08 Oct 2020 23:58:13
User entered 'None (0)'	System	08 Oct 2020 23:58:13

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:15**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-08T18:57:55', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'a8f13fa9-725a-4b4d-a144-b656253e3f5b'	System	08 Oct 2020 23:58:13
User entered 'None (0)'	System	08 Oct 2020 23:58:13

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:15**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-08T18:57:57', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'a8f13fa9-725a-4b4d-a144-b656253e3f5b'	System	08 Oct 2020 23:58:13
User entered 'None (0)'	System	08 Oct 2020 23:58:13



**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:15**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-08T18:57:59', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'a8f13fa9-725a-4b4d-a144-b656253e3f5b'	System	08 Oct 2020 23:58:13
User entered 'None (0)'	System	08 Oct 2020 23:58:13

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:15**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-08T18:58:01', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'a8f13fa9-725a-4b4d-a144-b656253e3f5b'	System	08 Oct 2020 23:58:13
User entered 'None (0)'	System	08 Oct 2020 23:58:13

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:15**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-08T18:58:04', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'a8f13fa9-725a-4b4d-a144-b656253e3f5b'	System	08 Oct 2020 23:58:13
User entered 'None (0)'	System	08 Oct 2020 23:58:13

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:59:15

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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-08T18:58:06', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'a8f13fa9-725a-4b4d-a144-b656253e3f5b'	System	08 Oct 2020 23:58:13
User entered 'No (N)'	System	08 Oct 2020 23:58:13

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-10-08T18:58:09', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'a8f13fa9-725a-4b4d-a144-b656253e3f5b'	System	08 Oct 2020 23:58:13
User entered '08 Oct 2020 18:58'	System	08 Oct 2020 23:58:13

**US3362222**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 14:45:10

US3362222

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:59:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 14:45:10

US3362222

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 19:15:37



US3362222

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '9 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 19:15:37

US3362222

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Oct 2020 19:15:37

US3362222

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 19:15:37

US3362222

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 19:15:41

**US3362222**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:59:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Oct 2020 19:15:41

US3362222

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 19:33:27

US3362222

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 19:33:27

US3362222

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Oct 2020 19:33:27



**US3362222**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 19:33:27

US3362222

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 19:33:36

**US3362222**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:59:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Oct 2020 19:33:36

US3362222

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 19:34:18

US3362222

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 19:34:18

US3362222

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Oct 2020 19:34:18

**US3362222**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 19:34:18

US3362222

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 19:34:23



**US3362222**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:59:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Oct 2020 19:34:23

US3362222

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Nov 2020 14:51:06

US3362222

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '2 Nov 2020'	(b) (4), (b) (6)	02 Nov 2020 14:51:06

US3362222

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	02 Nov 2020 14:51:06

**US3362222**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:59:15**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	02 Nov 2020 14:51:06

US3362222

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Nov 2020 14:52:12

US3362222

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Nov 2020'	(b) (4), (b) (6)	02 Nov 2020 14:52:12

US3362222

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered '07:36'	(b) (4), (b) (6)	02 Nov 2020 14:52:12



**US3362222**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '2 Nov 2020 07:36'	System	02 Nov 2020 14:52:12

US3362222

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:15

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.7' C	(b) (4), (b) (6)	02 Nov 2020 14:52:12

US3362222

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:15

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	02 Nov 2020 14:52:12

US3362222

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:15

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Nov 2020 14:52:12

US3362222

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '71'	(b) (4), (b) (6)	02 Nov 2020 14:52:12

**US3362222**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:15**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Nov 2020 14:52:12

US3362222

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	02 Nov 2020 14:52:12

US3362222

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Nov 2020 14:52:12



US3362222

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '120'	(b) (4), (b) (6)	02 Nov 2020 14:52:12

**US3362222**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:15**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Nov 2020 14:52:12

US3362222

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '79'	(b) (4), (b) (6)	02 Nov 2020 14:52:12

**US3362222**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:15**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Nov 2020 14:52:12

US3362222

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:15

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Nov 2020 14:52:17

US3362222

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Nov 2020'	(b) (4), (b) (6)	02 Nov 2020 14:52:17

US3362222

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Nov 2020 14:52:30

US3362222

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Nov 2020'	(b) (4), (b) (6)	02 Nov 2020 14:52:30



US3362222

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '08:00'	(b) (4), (b) (6)	02 Nov 2020 14:52:30

US3362222

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '2 Nov 2020 08:00'	System	02 Nov 2020 14:52:30

US3362222

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Nov 2020 14:52:34

**US3362222**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:59:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Nov 2020 14:52:34

**US3362222**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered 'Day 64'	System	28 Aug 2020 21:59:12

**US3362222**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-11-01T21:40:37', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'a6d7b586-8578-46ff-920c-d8e80bb9fc3f'	System	02 Nov 2020 03:41:15
User entered 'Yes (Y)'	System	02 Nov 2020 03:41:15

**US3362222**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

Have you been exposed to someone with 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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-11-01T21:40:43', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'a6d7b586-8578-46ff-920c-d8e80bb9fc3f'	System	02 Nov 2020 03:41:15
User entered 'No (N)'	System	02 Nov 2020 03:41:15

US3362222

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:15

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-11-01T21:40:48', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'a6d7b586-8578-46ff-920c-d8e80bb9fc3f'	System	02 Nov 2020 03:41:15
User entered 'No (N)'	System	02 Nov 2020 03:41:15



**US3362222**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-11-01T21:40:55', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'a6d7b586-8578-46ff-920c-d8e80bb9fc3f' User entered 'Yes (Y)'	System	02 Nov 2020 03:41:15
	System	02 Nov 2020 03:41:15

**US3362222**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-11-01T21:41:01', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'a6d7b586-8578-46ff-920c-d8e80bb9fc3f'	System	02 Nov 2020 03:41:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Nov 2020 03:41:15

**US3362222**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-11-01T21:41:06', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'a6d7b586-8578-46ff-920c-d8e80bb9fc3f' User entered '01 Nov 2020 21:41:06'	System	02 Nov 2020 03:41:15
	System	02 Nov 2020 03:41:15

**US3362222**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered '28 Oct 2020 00:01'	System	28 Aug 2020 21:59:12

**US3362222**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered '01 Nov 2020 23:59'	System	28 Aug 2020 21:59:12

**US3362222**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered 'Day 71'	System	28 Aug 2020 21:59:12

**US3362222**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-11-06T12:03:53', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '98eacb84-b972-4de1-ab4d-57b31324a9e8'	System	06 Nov 2020 18:04:04
User entered 'No (N)'	System	06 Nov 2020 18:04:04

**US3362222**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

Have you been exposed to someone with 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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-11-06T12:03:55', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '98eacb84-b972-4de1-ab4d-57b31324a9e8'	System	06 Nov 2020 18:04:04
User entered 'No (N)'	System	06 Nov 2020 18:04:04



**US3362222**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-11-06T12:03:59', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '98eacb84-b972-4de1-ab4d-57b31324a9e8' User entered '06 Nov 2020 12:03:59'	System	06 Nov 2020 18:04:04
	System	06 Nov 2020 18:04:04

**US3362222**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered '04 Nov 2020 00:01'	System	28 Aug 2020 21:59:12

**US3362222**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered '08 Nov 2020 23:59'	System	28 Aug 2020 21:59:12

**US3362222**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered 'Day 78'	System	28 Aug 2020 21:59:12

**US3362222**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-11-12T14:23:55', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '021d5fca-f67e-4542-b086-cf20ee9ad1fa'	System	12 Nov 2020 20:24:04
User entered 'No (N)'	System	12 Nov 2020 20:24:04

**US3362222**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

Have you been exposed to someone with 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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-11-12T14:23:53', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '021d5fca-f67e-4542-b086-cf20ee9ad1fa' User entered 'No (N)'	System	12 Nov 2020 20:24:04

**US3362222**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-11-12T14:23:59', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: '021d5fca-f67e-4542-b086-cf20ee9ad1fa' User entered '12 Nov 2020 14:23:59'	System	12 Nov 2020 20:24:04
	System	12 Nov 2020 20:24:04

**US3362222**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered '11 Nov 2020 00:01'	System	28 Aug 2020 21:59:12



**US3362222**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 21:59:12
User entered '15 Nov 2020 23:59'	System	28 Aug 2020 21:59:12

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '25 Oct 2020 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '29 Oct 2020 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '01 Nov 2020 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '05 Nov 2020 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '08 Nov 2020 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '12 Nov 2020 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '15 Nov 2020 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '19 Nov 2020 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-11-22T19:43:28', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'b0d23fa3-eafb-4a63-af9d-90edd3aca40b'	System	23 Nov 2020 01:43:42
User entered 'No (N)'	System	23 Nov 2020 01:43:42

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Have you been exposed to someone with 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 (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-11-22T19:43:34', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'b0d23fa3-eafb-4a63-af9d-90edd3aca40b'	System	23 Nov 2020 01:43:42
User entered 'No (N)'	System	23 Nov 2020 01:43:42



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C67EB8F5-822A-4D0D-9515-7E5CCC957868)', Time: '2020-11-22T19:43:38', User OID: 'PatientReportedOutcome (US3362222)', ODM File OID: 'b0d23fa3-eafb-4a63-af9d-90edd3aca40b' User entered '22 Nov 2020 19:43:38'	System	23 Nov 2020 01:43:42

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:12:15



**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 01:12:15

**US3362222**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:12:15
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 01:12:15

US3362222

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:59:15

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 21:07:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Oct 2020 16:49:52
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 13:20:24

US3362222

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 16:05:19
User entered 'USA-US112-2020-mRNA-1273-P301000005'	System	26 Oct 2020 15:30:35
User entered 'New'	(b) (4), (b) (6)	26 Oct 2020 15:30:35

US3362222

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please update SAE term to diagnosis only (cholecystitis) without the procedure.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 18:30:33
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 15:25:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 15:25:50
Data point term sent to Coder	System	14 Nov 2020 15:24:54
Query 'PV Query: Please update SAE term to diagnosis only (cholecystitis) without the procedure.' answered with 'AE term updated to "Cholecystitis." ' (Site from Safety).	(b) (4), (b) (6)	14 Nov 2020 15:24:31
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 15:24:04
Coding entries removed.	(b) (4), (b) (6)	14 Nov 2020 15:24:04
User entered 'CHOLECYSTITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Nov 2020 15:24:04
User opened query 'PV Query: Please update SAE term to diagnosis only (cholecystitis) without the procedure.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 22:16:11
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 04:16:51
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 04:16:51
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
Data point term sent to Coder	System	04 Nov 2020 16:55:29
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	System	04 Nov 2020 16:54:33
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' answered with 'Cholecystectomy not an AE as this is a Concomitant procedure. ' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 16:54:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System). Data point term sent to Coder	Coder Import (b) (4)	03 Nov 2020 22:20:26
Coding entries removed.	System	03 Nov 2020 16:20:16
	Crystal Rowell (b) (4)	03 Nov 2020 16:19:42
User entered 'CHOLECYSTITIS with cholecystectomy' reason for change: Data Entry Error	Crystal Rowell (b) (4)	03 Nov 2020 16:19:42
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 19:16:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 19:16:34
Data point term sent to Coder	System	23 Oct 2020 19:15:51
User entered 'cholecystitis'	Crystal Rowell (b) (4)	23 Oct 2020 19:14:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	23 Oct 2020 19:14:53

US3362222

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	23 Oct 2020 19:14:53



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	23 Oct 2020 19:14:53

US3362222

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User closed query 'PV Query: Please consider updating the event start date to when the subject started to experience signs and symptom of extreme pain in her right upper abdomen (noted as 09 Oct 2020).' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 16:06:32
Query 'PV Query: Please consider updating the event start date to when the subject started to experience signs and symptom of extreme pain in her right upper abdomen (noted as 09 Oct 2020).' answered with 'UPDATED' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 17:05:49
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 17:05:41
User opened query 'PV Query: Please consider updating the event start date to when the subject started to experience signs and symptom of extreme pain in her right upper abdomen (noted as 09 Oct 2020).' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 14:50:08
User entered '10 Oct 2020'	Crystal Rowell (b) (4) (b) (4)	23 Oct 2020 19:14:53

US3362222

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User entered empty.	Crystal Rowell (b) (4)	23 Oct 2020 19:14:53
	(b) (4)	

**US3362222**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 19:14:53

**US3362222**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:15**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User entered 'No (N)'	Crystal Rowell (b) (4)	23 Oct 2020 19:14:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User entered '11 Oct 2020'	Crystal Rowell (b) (4) (b) (4)	23 Oct 2020 19:14:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User entered empty.	Crystal Rowell (b) (4)	23 Oct 2020 19:14:53
	(b) (4)	

**US3362222**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 19:14:53



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User entered 'Grade 4 (Grade 4)'	Crystal Rowell (b) (4) (b) (4)	23 Oct 2020 19:14:53

US3362222

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	23 Oct 2020 19:14:53

US3362222

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User entered '0'	Crystal Rowell (b) (4) (b) (4)	23 Oct 2020 19:14:53

US3362222

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User entered '0'	Crystal Rowell (b) (4)	23 Oct 2020 19:14:53
	(b) (4)	

US3362222

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User entered 'I'	Crystal Rowell (b) (4) (b) (4)	23 Oct 2020 19:14:53

US3362222

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User entered '10 Oct 2020'	Crystal Rowell (b) (4)	23 Oct 2020 19:14:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User entered '11 Oct 2020'	Crystal Rowell (b) (4) (b) (4)	23 Oct 2020 19:14:53

US3362222

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User entered 'No (N)'	Crystal Rowell (b) (4)	23 Oct 2020 19:14:53
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User entered empty.	Crystal Rowell (b) (4) (b) (4)	23 Oct 2020 19:14:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User entered '0'	Crystal Rowell (b) (4) (b) (4)	23 Oct 2020 19:14:53

US3362222

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User entered '0'	Crystal Rowell (b) (4) (b) (4)	23 Oct 2020 19:14:53

US3362222

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User entered '0'	Crystal Rowell (b) (4) (b) (4)	23 Oct 2020 19:14:53

US3362222

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User closed query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related. ' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 16:07:06
Query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 17:27:48
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 17:27:41
User opened query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related. ' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 15:22:32
User entered 'Not Applicable (NOT APPLICABLE)'	Crystal Rowell (b) (4) (b) (4)	23 Oct 2020 19:14:53

US3362222

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:44:01
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'update' (Site from DM).	Alexandra Caillouet (b) (4)	18 Nov 2020 17:16:52
DataPoint Un-verified.	Alexandra Caillouet (b) (4)	18 Nov 2020 17:16:45
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	18 Nov 2020 17:16:45
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 08:03:38
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User entered 'Not Applicable (NOT APPLICABLE)'	Crystal Rowell (b) (4) (b) (4)	23 Oct 2020 19:14:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User entered 'Not Applicable (NOT APPLICABLE)'	Crystal Rowell (b) (4)	23 Oct 2020 19:14:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User entered '0'	Crystal Rowell (b) (4) (b) (4)	23 Oct 2020 19:14:53



US3362222

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review response as there are Concomitant Medications recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 10:56:59
User entered '0'	Crystal Rowell (b) (4)	23 Oct 2020 19:14:53

US3362222

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User entered '1'	Crystal Rowell (b) (4) (b) (4)	23 Oct 2020 19:14:53

**US3362222**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:15**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Crystal Rowell (b) (4) (b) (4)	23 Oct 2020 19:14:53

US3362222

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User entered empty.	Crystal Rowell (b) (4) (b) (4)	23 Oct 2020 19:14:53

US3362222

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:15

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:06
User closed query 'PV Query: Please confirm the subject's age as EDC has 41 years old, however medical records mentioned 51 and 81 years old.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 16:07:12
Query 'PV Query: Please confirm the subject's age as EDC has 41 years old, however medical records mentioned 51 and 81 years old.' answered with 'subject is 51 years old; demographics page on EDC has 51 years old ' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 17:30:07
User opened query 'PV Query: Please confirm the subject's age as EDC has 41 years old, however medical records mentioned 51 and 81 years old.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 14:50:26
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	23 Oct 2020 19:16:38
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	23 Oct 2020 19:16:38
User entered 'patient started with RUQ abdominal pain on 09Oct2020, went to ER and admitted for treatment/surgical removal of gallbladder due to cholecystitis' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	23 Oct 2020 19:16:38
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	23 Oct 2020 19:14:53
User entered empty.	Crystal Rowell (b) (4) (b) (4)	23 Oct 2020 19:14:53

**US3362222**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Oct 2020 19:14:53

**US3362222**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Oct 2020 19:14:53

**US3362222**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Oct 2020 19:14:53



US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:59:15

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
User closed query 'Per CDM re-query: Thank you for your answer. Please keep this query open until con. meds are updated once information is available. Thank you!' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:58:00
Query 'Per CDM re-query: Thank you for your answer. Please keep this query open until con. meds are updated once information is available. Thank you!' answered with 'con meds have been updated! :)' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 20:17:28
User opened query 'Per CDM re-query: Thank you for your answer. Please keep this query open until con. meds are updated once information is available. Thank you!' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 06:09:58
User closed query 'Per CDM: Thank you for your answer. However, according to a entered data on "Diary Dose 1" Day 3, subject used medication to treat pain or fever. Please kindly consider if subject used medication for pain or fever during Day 3. Please review and update or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 06:09:58
Query 'Per CDM: Thank you for your answer. However, according to a entered data on "Diary Dose 1" Day 3, subject used medication to treat pain or fever. Please kindly consider if subject used medication for pain or fever during Day 3. Please review and update or clarify otherwise. Thank you!' answered with 'will be updated' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 14:41:49
User opened query 'Per CDM: Thank you for your answer. However, according to a entered data on "Diary Dose 1" Day 3, subject used medication to treat pain or fever. Please kindly consider if subject used medication for pain or fever during Day 3. Please review and update or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 06:11:53
User closed query 'Per CDM: According to a "Diary Dose 1", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 06:11:53

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:59:15

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Query 'Per CDM: According to a "Diary Dose 1", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' answered with 'no medication taken for diary dose 1 per diary review log in subject chart.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 14:10:18
User opened query 'Per CDM: According to a "Diary Dose 1", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 10:32:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:31:59

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: LEVOTHYROXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 17:33:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 17:33:57
Data point term sent to Coder	System	01 Sep 2020 17:33:17
User entered 'Levothyroxin'	(b) (4), (b) (6)	01 Sep 2020 17:32:41

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:32:41

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:15**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypothyroidism'	(b) (4), (b) (6)	01 Sep 2020 17:32:41

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '75'	(b) (4), (b) (6)	01 Sep 2020 17:32:41

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)'	(b) (4), (b) (6)	01 Sep 2020 17:32:41

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:32:41



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:15**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Sep 2020 17:32:41

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:32:41

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:15**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Sep 2020 17:32:41

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:32:41

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un Feb 2020'	(b) (4), (b) (6)	01 Sep 2020 17:32:41

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:32:41

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:32:41

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:32:41



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:32:41

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 17:32:41

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 17:32:41

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 17:32:41

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 06:27:44
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 06:27:44
Data point term sent to Coder	System	01 Sep 2020 17:34:22
User entered 'Sumatriptin'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 17:33:39

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:33:39

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:15**

[Indication](#)

Audit	User	Time (GMT)
User entered 'migraine'	(b) (4), (b) (6)	01 Sep 2020 17:33:39

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	(b) (4), (b) (6)	01 Sep 2020 17:33:39



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Sep 2020 17:33:39

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:33:39

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:15**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	01 Sep 2020 17:33:39

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:33:39

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:15**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Sep 2020 17:33:39

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:33:39

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2015'	(b) (4), (b) (6)	01 Sep 2020 17:33:39

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:33:39



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:33:39

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:33:39

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:33:39

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:33:39

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:33:39

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:33:39

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: TOPIRAMATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:34:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:34:45
Data point term sent to Coder	System	01 Sep 2020 17:34:23
User entered 'topiramate'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 17:34:17

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 14:14:51
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:34:17



US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:15

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note this medication is not expected to be given as a treatment for migraine. It is typically used as prophylaxis for migraine. Please review and update indication or please clarify if used as treatment for migraine.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 18:44:52
Query 'Per DM CLR: Please note this medication is not expected to be given as a treatment for migraine. It is typically used as prophylaxis for migraine. Please review and update indication or please clarify if used as treatment for migraine.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 14:14:59
User opened query 'Per DM CLR: Please note this medication is not expected to be given as a treatment for migraine. It is typically used as prophylaxis for migraine. Please review and update indication or please clarify if used as treatment for migraine.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 14:33:21
User entered 'migraine'	(b) (4), (b) (6)	01 Sep 2020 17:34:17

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:15

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50' reason for change: New Information	(b) (4), (b) (6)	18 Sep 2020 14:10:49
User entered '100'	(b) (4), (b) (6)	01 Sep 2020 17:34:17

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Sep 2020 17:34:17

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:34:17

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:15**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)' reason for change:	(b) (4), (b) (6)	18 Sep 2020 14:10:49
New Information		
User entered 'twice daily (BID)'	(b) (4), (b) (6)	01 Sep 2020 17:34:17

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:34:17

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:15**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Sep 2020 17:34:17

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:34:17



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2010'	(b) (4), (b) (6)	01 Sep 2020 17:34:17

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:34:17

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:15

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	03 Nov 2020 15:29:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:34:17

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '28 Sep 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	03 Nov 2020 15:29:55
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:34:17

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:34:17

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 14:10:49
User entered '2'	System	01 Sep 2020 17:34:17

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 17:34:17

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 17:34:17



US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION, PRODUCTSYNONYM: BUPROPIONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 23:19:46
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 23:19:46
Data point term sent to Coder	System	01 Sep 2020 17:35:24
User entered 'bupoprione'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 17:34:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:34:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:15**

[Indication](#)

Audit	User	Time (GMT)
User entered 'anxiety'	(b) (4), (b) (6)	01 Sep 2020 17:34:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '300'	(b) (4), (b) (6)	01 Sep 2020 17:34:54

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:15

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Sep 2020 17:34:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:34:54

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:15

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Sep 2020 17:34:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:34:54



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:15**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Sep 2020 17:34:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:34:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2010'	(b) (4), (b) (6)	01 Sep 2020 17:34:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:34:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:34:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:34:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:34:54

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 17:34:54



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 17:34:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 17:34:54

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 22:11:40
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 22:11:40
Data point term sent to Coder	System	01 Sep 2020 17:36:28
User entered 'Albuterol 0.5-2.5mg/mL'	(b) (4), (b) (6) (b) (4)	01 Sep 2020 17:35:37

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:35:37

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:15**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Asthma'	(b) (4), (b) (6)	01 Sep 2020 17:35:37

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '2'	(b) (4), (b) (6)	01 Sep 2020 17:35:37

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'puff (PUFF)'	(b) (4), (b) (6)	01 Sep 2020 17:35:37

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:35:37



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:15**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	01 Sep 2020 17:35:37

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:35:37

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:15**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	01 Sep 2020 17:35:37

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:35:37

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2014'	(b) (4), (b) (6)	01 Sep 2020 17:35:37

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:35:37

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:35:37

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:35:37



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:35:37

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:35:37

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:35:37

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 17:35:37

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:15

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: DULOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: CYMBALTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 20:09:29
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 20:09:29
Data point term sent to Coder	System	03 Nov 2020 15:29:59
Coding entries removed.	Crystal Rowell (b) (4) (b) (4)	03 Nov 2020 15:29:16
User entered 'CYMBALTA' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	03 Nov 2020 15:29:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: DULOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: CYMBALTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 15:03:59
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 15:03:59
Data point term sent to Coder	System	18 Sep 2020 14:12:02
User entered 'Symbalta'	(b) (4), (b) (6) (b) (4)	18 Sep 2020 14:11:48

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Prophylaxis= YES. Please review if this should to 'NO' as there is an ongoing MH (Migraine) that corresponds to this indication.Please update response as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 17:01:19
Query 'Per DM CLR: Prophylaxis= YES. Please review if this should to 'NO' as there is an ongoing MH (Migraine) that corresponds to this indication.Please update response as appropriate. ' answered with 'no. Treating Ongoing MH ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 19:13:56
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 19:13:28
User opened query 'Per DM CLR: Prophylaxis= YES. Please review if this should to 'NO' as there is an ongoing MH (Migraine) that corresponds to this indication.Please update response as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 06:23:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 14:11:48

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:15**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Medical History Migraine prophylaxis'	(b) (4), (b) (6)	18 Sep 2020 14:11:48

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '60'	(b) (4), (b) (6)	18 Sep 2020 14:11:48



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	18 Sep 2020 14:11:48

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 14:11:48

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:15**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	18 Sep 2020 14:11:48

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 14:11:48

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:15**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	18 Sep 2020 14:11:48

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 14:11:48

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:15

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 14:11:48

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 14:11:48



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 14:11:48

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 14:11:48

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 14:11:48

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 14:11:48

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 14:11:48

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 14:11:48

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 19:38:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 19:38:25
Data point term sent to Coder	System	13 Oct 2020 19:37:12
Coding entries removed.	(b) (4), (b) (6)	13 Oct 2020 19:37:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 14:26:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 14:26:30
Data point term sent to Coder	System	09 Oct 2020 14:25:37
Data point term sent to Coder	System	09 Oct 2020 14:24:34
User entered 'Tylenol'	(b) (4), (b) (6)	09 Oct 2020 14:24:03

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 14:24:03



US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:15

[Indication](#)

Audit	User	Time (GMT)
User entered 'HEADACHE, PAIN AT INJECTION SITE, MUSCLE ACHES, FATIGUE, to treat/prevent pain/fever from occurring/already occurred.' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 19:37:07
User entered 'HEADACHE, PAIN AT INJECTION SITE, MUSCLE ACHES, FATIGUE' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 14:24:44
User entered 'Headache, pain at injection site'	(b) (4), (b) (6)	09 Oct 2020 14:24:03

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1000'	(b) (4), (b) (6)	09 Oct 2020 14:24:03

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Oct 2020 14:24:03

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:59:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 14:24:03

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:15

[Frequency](#)

Audit	User	Time (GMT)
User entered 'four times daily (QID)'	(b) (4), (b) (6)	09 Oct 2020 14:24:03

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:59:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 14:24:03

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:59:15**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Oct 2020 14:24:03

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:59:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 14:24:03



US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:15

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '3 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 14:24:03

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 14:24:03

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:15

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 14:24:03

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:59:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered '4 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 14:24:03

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:59:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 14:24:03

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:59:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	09 Oct 2020 14:24:03

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 14:24:03

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Oct 2020 14:24:03



US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 11:52:36
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 11:52:36
Data point term sent to Coder	System	03 Nov 2020 15:34:06
Data point term sent to Coder	System	02 Nov 2020 14:55:57
User entered 'Oxycodone'	(b) (4), (b) (6) (b) (4)	02 Nov 2020 14:55:03

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	03 Nov 2020 15:33:27
User entered 'No (N)'	(b) (4), (b) (6)	02 Nov 2020 14:55:03

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:15

[Indication](#)

Audit	User	Time (GMT)
User entered 'post operative pain/prevention' reason for change: Data Entry Error	Crystal Rowell (b) (4)	03 Nov 2020 15:33:27
User entered 'Cholelithiasis'	(b) (4), (b) (6)	02 Nov 2020 14:55:03

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5'	(b) (4), (b) (6)	02 Nov 2020 14:55:03

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Nov 2020 14:55:03

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Nov 2020 14:55:03

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:15**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	02 Nov 2020 14:55:03

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Nov 2020 14:55:03



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:15**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Nov 2020 14:55:03

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Nov 2020 14:55:03

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020'	(b) (4), (b) (6)	02 Nov 2020 14:55:03

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Nov 2020 14:55:03

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Nov 2020 14:55:03

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '12 Oct 2020'	(b) (4), (b) (6)	02 Nov 2020 14:55:03

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Nov 2020 14:55:03

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 14:55:03



**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 14:55:03

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 14:55:03

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:15

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 15:48:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 15:48:40
Data point term sent to Coder	System	03 Nov 2020 15:33:05
Data point term sent to Coder	System	03 Nov 2020 15:32:04
Data point term sent to Coder	System	02 Nov 2020 14:58:03
User entered 'Colace'	(b) (4), (b) (6) (b) (4)	02 Nov 2020 14:58:02

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	03 Nov 2020 15:31:23
User entered 'No (N)'	(b) (4), (b) (6)	02 Nov 2020 14:58:02

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:15

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 15:32:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 15:32:15
User entered 'constipation prevention' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	03 Nov 2020 15:32:15
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 15:31:23
User entered empty; reason for change Data Entry Error	Crystal Rowell (b) (4) (b) (4)	03 Nov 2020 15:31:23
User entered 'Cholelithias'	(b) (4), (b) (6) (b) (4)	02 Nov 2020 14:58:02

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	(b) (4), (b) (6)	02 Nov 2020 14:58:02

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Nov 2020 14:58:02

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Nov 2020 14:58:02



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:15**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	(b) (4), (b) (6)	02 Nov 2020 14:58:02

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Nov 2020 14:58:02

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:15**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Nov 2020 14:58:02

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Nov 2020 14:58:02

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020'	(b) (4), (b) (6)	02 Nov 2020 14:58:02

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Nov 2020 14:58:02

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Nov 2020 14:58:02

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Nov 2020 14:58:02



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Nov 2020 14:58:02

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Nov 2020 14:58:02

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 14:58:02

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Nov 2020 14:58:02

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL, PRODUCTSYNONYM: ROBAXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 08:57:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 08:57:05
Data point term sent to Coder	System	02 Nov 2020 15:00:04
User entered 'Robaxin'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Nov 2020 14:59:54

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Nov 2020 14:59:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:59:15**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Cholelithiasis'	(b) (4), (b) (6)	02 Nov 2020 14:59:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	(b) (4), (b) (6)	02 Nov 2020 14:59:54



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Nov 2020 14:59:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:59:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Nov 2020 14:59:54

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:15

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Nov 2020 14:59:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:59:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Nov 2020 14:59:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:59:15**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Nov 2020 14:59:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:59:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Nov 2020 14:59:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020'	(b) (4), (b) (6)	02 Nov 2020 14:59:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Nov 2020 14:59:54



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:59:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Nov 2020 14:59:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:59:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '17 Oct 2020'	(b) (4), (b) (6)	02 Nov 2020 14:59:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:59:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Nov 2020 14:59:54

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:59:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 14:59:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 14:59:54

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Nov 2020 14:59:54

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, QUATERNARY AMMONIUM COMPOUNDS, PRODUCT: GLYCOPYRRONIUM, PRODUCTSYNONYM: GLYCOPYRROLATE [GLYCOPYRRONIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:16:27
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:16:27
Data point term sent to Coder	System	03 Nov 2020 17:18:45
User entered 'Glycopyrrolate'	(b) (4), (b) (6)	03 Nov 2020 17:18:08

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:18:08



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:15**

[Indication](#)

Audit	User	Time (GMT)
User entered 'cholecystectomy'	(b) (4), (b) (6)	03 Nov 2020 17:18:08

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.8'	(b) (4), (b) (6)	03 Nov 2020 17:18:08

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Nov 2020 17:18:08

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:18:08

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:15

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 17:30:47
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 Nov 2020 17:18:08

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:18:08

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:15**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	03 Nov 2020 17:18:08

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:18:08



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:18:08

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:18:08

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:15

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:18:08

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:18:08

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:18:08

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:30:47
User entered '1'	System	03 Nov 2020 17:18:08

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:30:47
User entered '1'	System	03 Nov 2020 17:18:08

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:30:47
User entered '804 (804)'	System	03 Nov 2020 17:18:08



US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:25:22
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:25:22
Data point term sent to Coder	System	03 Nov 2020 17:19:46
User entered 'Ketorolac'	(b) (4), (b) (6) (b) (4)	03 Nov 2020 17:19:39

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:59:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:19:39

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:59:15**

[Indication](#)

Audit	User	Time (GMT)
User entered 'cholecystectomy'	(b) (4), (b) (6)	03 Nov 2020 17:19:39

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '30'	(b) (4), (b) (6)	03 Nov 2020 17:19:39

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Nov 2020 17:19:39

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:59:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:19:39

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:15

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 17:30:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 Nov 2020 17:19:39

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:59:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:19:39



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:59:15**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	03 Nov 2020 17:19:39

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:59:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:19:39

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:19:39

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:19:39

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:59:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:19:39

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:59:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:19:39

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:59:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:19:39

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:59:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:30:57
User entered '1'	System	03 Nov 2020 17:19:39



**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:30:57
User entered '1'	System	03 Nov 2020 17:19:39

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:30:57
User entered '804 (804)'	System	03 Nov 2020 17:19:39

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:59:15

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Nov 2020 19:09:24
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Nov 2020 19:09:24
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Nov 2020 18:54:23
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Nov 2020 18:54:23
Data point term sent to Coder	System	03 Nov 2020 18:43:45
User closed query 'For coding purposes, term is not codable as entered. Please clarify the Con Med DEXAMTHAGUNE. If correct spelling, please provide the active ingredient, generic/trade name and update the term with your response' (Site from System).	System	03 Nov 2020 18:43:36
Query 'For coding purposes, term is not codable as entered. Please clarify the Con Med DEXAMTHAGUNE. If correct spelling, please provide the active ingredient, generic/trade name and update the term with your response' answered with 'spelling corrected' (Site from System).	(b) (4), (b) (6)	03 Nov 2020 18:43:36
User entered 'Dexamethasone' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 18:43:21

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:59:15

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'For coding purposes, term is not codable as entered. Please clarify the Con Med DEXAMTHAGUNE. If correct spelling, please provide the active ingredient, generic/trade name and update the term with your response' (Site from System).	Coder Import (b) (4)	03 Nov 2020 18:12:22
Data point term sent to Coder	System	03 Nov 2020 17:21:49
User entered 'Dexamthagune'	(b) (4), (b) (6)	03 Nov 2020 17:21:15

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:59:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:21:15

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:59:15**

[Indication](#)

Audit	User	Time (GMT)
User entered 'cholecystectomy'	(b) (4), (b) (6)	03 Nov 2020 17:21:15

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '4'	(b) (4), (b) (6)	03 Nov 2020 17:21:15

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Nov 2020 17:21:15



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:59:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:21:15

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:59:15

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 17:31:08
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 Nov 2020 17:21:15

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:59:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:21:15

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:59:15**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	03 Nov 2020 17:21:15

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:59:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:21:15

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:21:15

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:21:15

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:59:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:21:15



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:59:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:21:15

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:59:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:21:15

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:59:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:31:08
User entered '1'	System	03 Nov 2020 17:21:15

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:31:08
User entered '1'	System	03 Nov 2020 17:21:15

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:31:08
User entered '804 (804)'	System	03 Nov 2020 17:21:15

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:59:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:15:24
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:15:24
Data point term sent to Coder	System	03 Nov 2020 17:25:53
User entered 'Lactated rigors'	(b) (4), (b) (6) (b) (4)	03 Nov 2020 17:24:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:59:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:24:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:59:15**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Cholecystectomy'	(b) (4), (b) (6)	03 Nov 2020 17:24:54



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1200'	(b) (4), (b) (6)	03 Nov 2020 17:24:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	(b) (4), (b) (6)	03 Nov 2020 17:24:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:59:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:24:54

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:59:15

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 17:31:23
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 Nov 2020 17:24:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:59:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:24:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:59:15**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	03 Nov 2020 17:24:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:59:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:24:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:24:54



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:24:54

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:59:15

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:24:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:59:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:24:54

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:59:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:24:54

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:59:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:31:23
User entered '1'	System	03 Nov 2020 17:24:54

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:31:23
User entered '1'	System	03 Nov 2020 17:24:54

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:31:23
User entered '804 (804)'	System	03 Nov 2020 17:24:54

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:59:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:51:25
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:51:25
Data point term sent to Coder	System	03 Nov 2020 17:29:00
User entered 'Propofol'	(b) (4), (b) (6)	03 Nov 2020 17:28:52



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:59:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:28:52

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:59:15**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Cholithiasismis/ Cholecystectomy'	(b) (4), (b) (6)	03 Nov 2020 17:28:52

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '80'	(b) (4), (b) (6)	03 Nov 2020 17:28:52

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Nov 2020 17:28:52

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:59:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:28:52

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:59:15

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 17:32:07
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 Nov 2020 17:28:52

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:59:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:28:52

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:59:15**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	03 Nov 2020 17:28:52



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:59:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:28:52

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:28:52

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:28:52

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:59:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:28:52

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:59:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:28:52

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:59:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:28:52

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:59:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:32:07
User entered '1'	System	03 Nov 2020 17:28:52

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:32:07
User entered '1'	System	03 Nov 2020 17:28:52



**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:32:07
User entered '804 (804)'	System	03 Nov 2020 17:28:52

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:59:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:35:23
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:35:23
Data point term sent to Coder	System	03 Nov 2020 17:31:04
User entered 'lidocaine'	(b) (4), (b) (6) (b) (4)	03 Nov 2020 17:30:23

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:59:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:30:23

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:59:15**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Cholithiasismis/ Cholecystectomy'	(b) (4), (b) (6)	03 Nov 2020 17:30:23

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	(b) (4), (b) (6)	03 Nov 2020 17:30:23

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Nov 2020 17:30:23

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:59:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:30:23

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:59:15**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(b) (4), (b) (6)	03 Nov 2020 17:30:23



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:59:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:30:23

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:59:15**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	03 Nov 2020 17:30:23

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:59:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:30:23

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:30:23

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:30:23

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:59:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:30:23

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:59:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:30:23

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:59:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:30:23



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:59:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:30:23

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:30:23

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:30:23

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:59:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER QUATERNARY AMMONIUM COMPOUNDS, PRODUCT: ROCURONIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 19:06:24
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 19:06:24
Data point term sent to Coder	System	03 Nov 2020 17:34:10
User entered 'Rocuronium'	(b) (4), (b) (6) (b) (4)	03 Nov 2020 17:33:10

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:59:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 17:36:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 17:36:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 17:36:30
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 17:33:10
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:33:10

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:59:15**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Cholithiasismis/ Cholecystectomy'	(b) (4), (b) (6)	03 Nov 2020 17:33:10

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	(b) (4), (b) (6)	03 Nov 2020 17:33:10

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Nov 2020 17:33:10



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:59:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:33:10

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:59:15

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(b) (4), (b) (6)	03 Nov 2020 17:33:10

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:59:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:33:10

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:59:15**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	03 Nov 2020 17:33:10

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:59:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:33:10

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:33:10

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:33:10

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:59:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:33:10



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:59:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:33:10

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:59:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:33:10

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:59:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:33:10

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:33:10

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:33:10

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:59:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 00:29:36
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 00:29:36
Data point term sent to Coder	System	03 Nov 2020 17:35:12
User entered 'Zofran'	(b) (4), (b) (6) (b) (4)	03 Nov 2020 17:34:58

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:59:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:34:58

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:59:15**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Cholithiasismis/ Cholecystectomy'	(b) (4), (b) (6)	03 Nov 2020 17:34:58



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '4'	(b) (4), (b) (6)	03 Nov 2020 17:34:58

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Nov 2020 17:34:58

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:59:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:34:58

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:59:15**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(b) (4), (b) (6)	03 Nov 2020 17:34:58

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:59:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:34:58

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:59:15**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	03 Nov 2020 17:34:58

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:59:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:34:58

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:34:58



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:34:58

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:59:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:34:58

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:59:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:34:58

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:59:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:34:58

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:59:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:34:58

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:34:58

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:34:58

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:59:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: PARASYMPATHOMIMETICS, ATC: ANTICHOLINESTERASES, PRODUCT: NEOSTIGMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:48:28
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:48:28
Data point term sent to Coder	System	03 Nov 2020 17:36:13
User entered 'Neostigmine'	(b) (4), (b) (6) (b) (4)	03 Nov 2020 17:35:46



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:59:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:35:46

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:59:15**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Cholithiasismis/ Cholecystectomy'	(b) (4), (b) (6)	03 Nov 2020 17:35:46

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5'	(b) (4), (b) (6)	03 Nov 2020 17:35:46

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Nov 2020 17:35:46

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:59:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:35:46

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:59:15**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(b) (4), (b) (6)	03 Nov 2020 17:35:46

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:59:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:35:46

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:59:15**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	03 Nov 2020 17:35:46



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:59:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:35:46

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:35:46

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:35:46

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:59:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:35:46

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:59:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:35:46

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:59:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:35:46

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:59:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:35:46

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:35:46



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:35:46

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:59:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 00:15:27
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 00:15:27
Data point term sent to Coder	System	03 Nov 2020 17:41:19
User entered 'Zofran'	(b) (4), (b) (6) (b) (4)	03 Nov 2020 17:40:56

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:59:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 17:40:56

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:59:15**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Nausea Prevention'	(b) (4), (b) (6)	03 Nov 2020 17:40:56

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '4'	(b) (4), (b) (6)	03 Nov 2020 17:40:56

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Nov 2020 17:40:56

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:59:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:40:56

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:59:15**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	03 Nov 2020 17:40:56



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:59:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:40:56

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:59:15**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Nov 2020 17:40:56

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:59:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:40:56

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:40:56

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:40:56

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:59:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:40:56

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:59:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '12 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:40:56

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:59:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:40:56



**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:59:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:40:56

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:40:56

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:40:56

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:59:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:40:23
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:40:23
Data point term sent to Coder	System	03 Nov 2020 17:44:24
User entered 'Midazolam'	(b) (4), (b) (6) (b) (4)	03 Nov 2020 17:43:43

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 26 Nov 2020 10:59:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:43:43

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 26 Nov 2020 10:59:15**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Cholithiasismis/ Cholecystectomy'	(b) (4), (b) (6)	03 Nov 2020 17:43:43

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '2'	(b) (4), (b) (6)	03 Nov 2020 17:43:43

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Nov 2020 17:43:43



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 26 Nov 2020 10:59:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:43:43

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 26 Nov 2020 10:59:15**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(b) (4), (b) (6)	03 Nov 2020 17:43:43

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 26 Nov 2020 10:59:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:43:43

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 26 Nov 2020 10:59:15**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	03 Nov 2020 17:43:43

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 26 Nov 2020 10:59:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:43:43

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:43:43

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:43:43

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:59:15

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:43:43



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 26 Nov 2020 10:59:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:43:43

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 26 Nov 2020 10:59:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:43:43

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 26 Nov 2020 10:59:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:43:43

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:43:43

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:43:43

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 10:59:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:14:32
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:14:32
Data point term sent to Coder	System	03 Nov 2020 17:51:29
User entered 'Fentanyl'	(b) (4), (b) (6) (b) (4)	03 Nov 2020 17:50:35

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 26 Nov 2020 10:59:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:50:35

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 26 Nov 2020 10:59:15**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Cholecystectomy'	(b) (4), (b) (6)	03 Nov 2020 17:50:35



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	(b) (4), (b) (6)	03 Nov 2020 17:50:35

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	(b) (4), (b) (6)	03 Nov 2020 17:50:35

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 26 Nov 2020 10:59:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'mcg'	(b) (4), (b) (6)	03 Nov 2020 17:50:35

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 26 Nov 2020 10:59:15**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(b) (4), (b) (6)	03 Nov 2020 17:50:35

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 26 Nov 2020 10:59:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:50:35

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 26 Nov 2020 10:59:15**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	03 Nov 2020 17:50:35

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 26 Nov 2020 10:59:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:50:35

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:50:35



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:50:35

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 26 Nov 2020 10:59:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:50:35

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 26 Nov 2020 10:59:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:50:35

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 26 Nov 2020 10:59:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:50:35

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 26 Nov 2020 10:59:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:50:35

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:50:35

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:50:35

US3362222

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 10:59:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:14:32
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:14:32
Data point term sent to Coder	System	03 Nov 2020 17:52:30
User entered 'Fentanyl'	(b) (4), (b) (6) (b) (4)	03 Nov 2020 17:52:04



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 26 Nov 2020 10:59:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:52:04

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 26 Nov 2020 10:59:15**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Cholecystectomy'	(b) (4), (b) (6)	03 Nov 2020 17:52:04

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '150'	(b) (4), (b) (6)	03 Nov 2020 17:52:04

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 26 Nov 2020 10:59:15**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	(b) (4), (b) (6)	03 Nov 2020 17:52:04

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 26 Nov 2020 10:59:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'mcg'	(b) (4), (b) (6)	03 Nov 2020 17:52:04

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 26 Nov 2020 10:59:15**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(b) (4), (b) (6)	03 Nov 2020 17:52:04

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 26 Nov 2020 10:59:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:52:04

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 26 Nov 2020 10:59:15**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	03 Nov 2020 17:52:04



US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 26 Nov 2020 10:59:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:52:04

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:52:04

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 26 Nov 2020 10:59:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:52:04

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 26 Nov 2020 10:59:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:52:04

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 26 Nov 2020 10:59:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:52:04

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 26 Nov 2020 10:59:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:52:04

US3362222

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 26 Nov 2020 10:59:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:52:04

**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:52:04



**US3362222**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 26 Nov 2020 10:59:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:52:04

US3362222

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 10:59:15**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	23 Oct 2020 19:16:48
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 13:20:15

US3362222

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 10:59:15**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Oct 2020'	Crystal Rowell (b) (4) (b) (4)	23 Oct 2020 19:17:17

US3362222

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 10:59:15**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'cholecystectomy'	Crystal Rowell (b) (4) (b) (4)	23 Oct 2020 19:17:17

US3362222

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 10:59:15**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Crystal Rowell (b) (4) (b) (4)	23 Oct 2020 19:17:17

US3362222

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 10:59:15**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	23 Oct 2020 19:17:17

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'USA-US112-2020-MRNA-1273-P301000005'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'Yes (Y)'	System	26 Oct 2020 15:30:35



**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'Yes (Y)'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'Jordan'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'Whatley'	System	26 Oct 2020 15:30:35



**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered '5326 O'donovan dr'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'baton rouge'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 16:15:19
Un-reviewed for Safety.	System	03 Nov 2020 16:10:37
User entered empty.	System	03 Nov 2020 16:10:37
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 16:09:27
User entered 'Louisiana'	Crystal Rowell (b) (4)	03 Nov 2020 15:10:51
	(b) (4)	

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered '70808'	System	26 Oct 2020 15:30:35

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 16:09:27
User entered 'US'	System	26 Oct 2020 15:30:49

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Nov 2020 14:32:36
User entered '4'	System	16 Nov 2020 18:31:32
User entered '3'	System	04 Nov 2020 13:30:52
User entered '2'	System	03 Nov 2020 16:10:37
User entered '1'	System	26 Oct 2020 15:30:49

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'USA-US112-2020-MRNA-1273-P301000005'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'Yes (Y)'	System	26 Oct 2020 15:30:35



**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'Yes (Y)'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'Jordan'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'Whatley'	System	26 Oct 2020 15:30:35



**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered '5326 O'donovan dr'	System	26 Oct 2020 15:30:35

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'baton rouge'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 16:15:19
Un-reviewed for Safety.	System	03 Nov 2020 16:10:37
User entered empty.	System	03 Nov 2020 16:10:37
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 16:09:27
User entered 'Louisiana'	Crystal Rowell (b) (4)	03 Nov 2020 15:10:51
	(b) (4)	

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered '70808'	System	26 Oct 2020 15:30:35

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 16:09:27
User entered 'US'	System	26 Oct 2020 15:30:49

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Nov 2020 14:32:36
User entered '4'	System	16 Nov 2020 18:31:32
User entered '3'	System	04 Nov 2020 13:30:52
User entered '2'	System	03 Nov 2020 16:10:37
User entered '1'	System	26 Oct 2020 15:30:49

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (1)**

**Generated On: 26 Nov 2020 10:59:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
User entered '26/Oct/2020 11:30'	System	26 Oct 2020 15:30:49

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:59:15

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 16:09:27
User entered 'I'	(b) (4), (b) (6)	26 Oct 2020 15:30:49



**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'USA-US112-2020-MRNA-1273-P301000005'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'Yes (Y)'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'Yes (Y)'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35



US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'Jordan'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'Whatley'	System	26 Oct 2020 15:30:35

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered '5326 O'donovan dr'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'baton rouge'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 16:15:19
Un-reviewed for Safety.	System	03 Nov 2020 16:10:37
User entered empty.	System	03 Nov 2020 16:10:37
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 16:09:27
User entered 'Louisiana'	Crystal Rowell (b) (4)	03 Nov 2020 15:10:51
	(b) (4)	

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered '70808'	System	26 Oct 2020 15:30:35

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 16:09:27
User entered 'US'	System	26 Oct 2020 15:30:49

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Nov 2020 14:32:36
User entered '4'	System	16 Nov 2020 18:31:32
User entered '3'	System	04 Nov 2020 13:30:52
User entered '2'	System	03 Nov 2020 16:10:37
User entered '1'	System	26 Oct 2020 15:30:49



**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (2)**

**Generated On: 26 Nov 2020 10:59:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
User entered '03/Nov/2020 16:10'	System	03 Nov 2020 16:10:37

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:59:15

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 16:15:19
User entered 'I'	(b) (4), (b) (6)	03 Nov 2020 16:10:37

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'USA-US112-2020-MRNA-1273-P301000005'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'Yes (Y)'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'Yes (Y)'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35



US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'Jordan'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'Whatley'	System	26 Oct 2020 15:30:35

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered '5326 O'donovan dr'	System	26 Oct 2020 15:30:35

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'baton rouge'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 16:15:19
Un-reviewed for Safety.	System	03 Nov 2020 16:10:37
User entered empty.	System	03 Nov 2020 16:10:37
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 16:09:27
User entered 'Louisiana'	Crystal Rowell (b) (4)	03 Nov 2020 15:10:51
	(b) (4)	

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered '70808'	System	26 Oct 2020 15:30:35



**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 16:09:27
User entered 'US'	System	26 Oct 2020 15:30:49

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Nov 2020 14:32:36
User entered '4'	System	16 Nov 2020 18:31:32
User entered '3'	System	04 Nov 2020 13:30:52
User entered '2'	System	03 Nov 2020 16:10:37
User entered '1'	System	26 Oct 2020 15:30:49

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (3)**

**Generated On: 26 Nov 2020 10:59:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
User entered '04/Nov/2020 13:30'	System	04 Nov 2020 13:30:52

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:59:15

**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 18:30:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
User entered 'I'	(b) (4), (b) (6)	04 Nov 2020 13:30:52

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'USA-US112-2020-MRNA-1273-P301000005'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'Yes (Y)'	System	26 Oct 2020 15:30:35

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35



**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'Yes (Y)'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'Jordan'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'Whatley'	System	26 Oct 2020 15:30:35

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered '5326 O'donovan dr'	System	26 Oct 2020 15:30:35

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'baton rouge'	System	26 Oct 2020 15:30:35



US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 16:15:19
Un-reviewed for Safety.	System	03 Nov 2020 16:10:37
User entered empty.	System	03 Nov 2020 16:10:37
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 16:09:27
User entered 'Louisiana'	Crystal Rowell (b) (4)	03 Nov 2020 15:10:51
	(b) (4)	

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered '70808'	System	26 Oct 2020 15:30:35

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 16:09:27
User entered 'US'	System	26 Oct 2020 15:30:49

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Nov 2020 14:32:36
User entered '4'	System	16 Nov 2020 18:31:32
User entered '3'	System	04 Nov 2020 13:30:52
User entered '2'	System	03 Nov 2020 16:10:37
User entered '1'	System	26 Oct 2020 15:30:49

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (4)**

**Generated On: 26 Nov 2020 10:59:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '16/Nov/2020 13:31'	System	16 Nov 2020 18:31:32

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:59:15

**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)	19 Nov 2020 14:32:03
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 18:31:32

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'USA-US112-2020-MRNA-1273-P301000005'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'Yes (Y)'	System	26 Oct 2020 15:30:35



**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'Yes (Y)'	System	26 Oct 2020 15:30:35

US3362222

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'No (N)'	System	26 Oct 2020 15:30:35

US3362222

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'Jordan'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'Whatley'	System	26 Oct 2020 15:30:35



**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered '5326 O'donovan dr'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered 'baton rouge'	System	26 Oct 2020 15:30:35

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:15

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 16:15:19
Un-reviewed for Safety.	System	03 Nov 2020 16:10:37
User entered empty.	System	03 Nov 2020 16:10:37
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 16:09:27
User entered 'Louisiana'	Crystal Rowell (b) (4)	03 Nov 2020 15:10:51
	(b) (4)	

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:30:42
User entered '70808'	System	26 Oct 2020 15:30:35

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:14:30
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 16:09:27
User entered 'US'	System	26 Oct 2020 15:30:49

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Nov 2020 14:32:36
User entered '4'	System	16 Nov 2020 18:31:32
User entered '3'	System	04 Nov 2020 13:30:52
User entered '2'	System	03 Nov 2020 16:10:37
User entered '1'	System	26 Oct 2020 15:30:49

**US3362222**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (5)**

**Generated On: 26 Nov 2020 10:59:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '19/Nov/2020 14:32'	System	19 Nov 2020 14:32:36

US3362222

Folder: SAE USA-US112-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 10:59:15

**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)	19 Nov 2020 14:32:36