

US3402448 (Prod: Meridian Clinical Research, LLC)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:23:21

All time stamps listed in this document are displayed in GMT

US3402448

Form: Participant Creation

Generated On: 26 Nov 2020 09:23:21

[Participant ID](#)

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

US3402448

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:21

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	21 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:21

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	66
Age Units	YEARS
Age (Derived)	66
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
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 09:23:21

Date of Informed Consent (<i>dd MMM yyyy</i>)	21 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☐
	Amendment 3 ☐
	Amendment 4 ☒
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:23:21

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:23:21

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:21

Condition	EMPHYSEMA
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒
	No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:21

Condition	HYPERCHOLESTERDEMIA
Start date (dd MMM yyyy)	UN UNK 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:21

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:21

Condition	SCHIZOAFFECTIVE DISORDER
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:21

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:21

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:21

Condition	HIATAL HERNIA
Start date (dd MMM yyyy)	UN MAY 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:21

Condition	LEFT KNEE ARTHOSCOPY
Start date (dd MMM yyyy)	UN APR 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:21

Condition	LEFT KNEE ARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:21

Condition	OVERACTIVE BLADDER
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:23:21

Condition	TOTAL HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:21

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	21 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	16:28 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 16:28
Height (<i>xxx.x</i>)	157.5 cm
Weight (<i>xxx.x</i>)	84.4 kg
BMI (<i>xxx.x</i>)	34.02368 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	74 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 OCT 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:21

Date of assessment (<i>dd MMM yyyy</i>)	21 OCT 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 (<i>dd MMM yyyy</i>)	UN UNK 2001
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:21

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

FREQUENTLY GOES TO STORES
AND RESTAURANTS

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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

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Folder: Screening

Form: Risk of Exposure

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Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:21

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	21 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:21

What was the date of randomization? (dd MMM yyyy) 21 OCT 2020

What was the participant's randomization number? 187792

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 09:23:21

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	16:28 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 16:28
Temperature (xxx.x)	36.8 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	18:02 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 18:02
Temperature (xxx.x)	37.0 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:21

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:21

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 21 OCT 2020

What was the treatment time? (00:00-23:59) 17:25 (24 HR)

Treatment Date and Time (derived) 21 OCT 2020 17:25

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:21

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	21 OCT 2020
Collection time (<i>00:00-23:59</i>)	18:02 (24 HR)
Collection date and time (derived)	21 OCT 2020 18:02

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:23:21

Collection date (<i>dd MMM yyyy</i>)			21 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	17:10	21 OCT 2020 17:10
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:23:21

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 09:23:21

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 OCT 2020 18:13

PC Open Date & Time

21 OCT 2020 15:45

PC Close Date & Time

21 OCT 2020 18:15

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 OCT 2020 21:14

PC Open Date & Time

21 OCT 2020 21:10

PC Close Date & Time

22 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:21

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

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 OCT 2020 19:27

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.4 °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

23 OCT 2020 13:26

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 OCT 2020 16:44

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:21

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

98.0 °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

25 OCT 2020 13:14

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

26 OCT 2020 16:06

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 OCT 2020 16:31

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

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

21 OCT 2020 18:14

PC Open Date & Time

21 OCT 2020 15:45

PC Close Date & Time

21 OCT 2020 18:15

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

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

21 OCT 2020 21:15

PC Open Date & Time

21 OCT 2020 21:10

PC Close Date & Time

22 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:21

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

22 OCT 2020 19:28

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 OCT 2020 13:27

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:21

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

24 OCT 2020 16:45

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:21

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

25 OCT 2020 13:15

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:21

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

26 OCT 2020 16:07

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:21

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

27 OCT 2020 16:31

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

21 OCT 2020 17:45

PC Close Date & Time

21 OCT 2020 20:15

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

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

No ☒

Yes ☐

PC Time stamp	21 OCT 2020 21:16
PC Open Date & Time	21 OCT 2020 21:10
PC Close Date & Time	22 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:21

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 ☒

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:21

Yes ☐	
PC Time stamp	22 OCT 2020 19:28
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:21

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 ☒

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:21

Yes ☐	
PC Time stamp	23 OCT 2020 13:27
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:21

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 ☒

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:21

Yes ☐	
PC Time stamp	24 OCT 2020 16:46
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:21

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 ☒

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:21

Yes ☐	
PC Time stamp	25 OCT 2020 13:16
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:21

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 ☒

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:21

Yes ☐	
PC Time stamp	26 OCT 2020 16:07
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:21

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 ☒

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:21

Yes ☐	
PC Time stamp	27 OCT 2020 16:32
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3402448

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402448

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402448

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402448

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402448

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 NOV 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

COULD NOT REACH SUBJECT.

If Contact Not Made, please provide Comments

US3402448

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402448

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:21

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	16 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	16 NOV 2020
Time of assessment (00:00-23:59)	13:03 (24 HR)
Vital Signs Date and Time (derived)	16 NOV 2020 13:03
Temperature (xxx.x)	36.4 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	16 NOV 2020
Time of assessment (00:00-23:59)	14:11 (24 HR)
Vital Signs Date and Time (derived)	16 NOV 2020 14:11
Temperature (xxx.x)	36.7 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3402448

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 NOV 2020

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

US3402448

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:21

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to Adverse Event ☐
	Physician withheld dose due to Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	16 NOV 2020
What was the treatment time? (00:00-23:59)	13:35 (24 HR)
Treatment Date and Time (derived)	16 NOV 2020 13:35
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3402448

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:21

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	16 NOV 2020
Collection time (<i>00:00-23:59</i>)	13:23 (24 HR)
Collection date and time (derived)	16 NOV 2020 13:23

US3402448

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:23:21

Collection date (dd MMM yyyy)			16 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:26	16 NOV 2020 13:26
Nasopharyngeal Swab 2	No		

US3402448

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

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

16 NOV 2020 14:21

PC Open Date & Time

16 NOV 2020 13:55

PC Close Date & Time

16 NOV 2020 16:25

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

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 98.0 °F

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

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

PC Time Stamp	17 NOV 2020 04:51
PC Open Date & Time	16 NOV 2020 17:20
PC Close Date & Time	17 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 NOV 2020 15:16

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 NOV 2020 16:43

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:21

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 NOV 2020 16:13

PC Open Date & Time

19 NOV 2020 12:00

PC Close Date & Time

20 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 NOV 2020 17:18

PC Open Date & Time

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 NOV 2020 12:03

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 NOV 2020 08:56

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

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

16 NOV 2020 14:22

PC Open Date & Time

16 NOV 2020 13:55

PC Close Date & Time

16 NOV 2020 16:25

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

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

17 NOV 2020 04:52

PC Open Date & Time

16 NOV 2020 17:20

PC Close Date & Time

17 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:21

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

17 NOV 2020 15:16

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 NOV 2020 16:43

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 NOV 2020 16:14

PC Open Date & Time

19 NOV 2020 12:00

PC Close Date & Time

20 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 NOV 2020 17:19

PC Open Date & Time

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 NOV 2020 12:04

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:21

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

23 NOV 2020 08:57

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

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

No ☒

Yes ☐

PC Time stamp	16 NOV 2020 14:22
PC Open Date & Time	16 NOV 2020 13:55
PC Close Date & Time	16 NOV 2020 16:25

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

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

No ☒

Yes ☐

PC Time stamp	17 NOV 2020 04:53
PC Open Date & Time	16 NOV 2020 17:20
PC Close Date & Time	17 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:21

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 ☒

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:21

Yes ☐	
PC Time stamp	17 NOV 2020 15:17
PC Open Date & Time	17 NOV 2020 12:00
PC Close Date & Time	18 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:21

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 ☒

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:21

Yes ☐	
PC Time stamp	18 NOV 2020 16:44
PC Open Date & Time	18 NOV 2020 12:00
PC Close Date & Time	19 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:21

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 ☒

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:21

Yes ☐	
PC Time stamp	19 NOV 2020 16:15
PC Open Date & Time	19 NOV 2020 12:00
PC Close Date & Time	20 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:21

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 ☒

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:21

Yes ☐	
PC Time stamp	20 NOV 2020 17:20
PC Open Date & Time	20 NOV 2020 12:00
PC Close Date & Time	21 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:21

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 ☒

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:21

Yes ☐	
PC Time stamp	21 NOV 2020 12:05
PC Open Date & Time	21 NOV 2020 12:00
PC Close Date & Time	22 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:21

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 ☒

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:21

Yes ☐	
PC Time stamp	23 NOV 2020 08:58
PC Open Date & Time	22 NOV 2020 12:00
PC Close Date & Time	23 NOV 2020 11:59

US3402448

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:21

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

US3402448

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:21

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐ 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐ 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐ 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

01 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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12 JAN 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

15 JAN 2021 00:01

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19 JAN 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐ 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2021 00:01

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26 JAN 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

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09 FEB 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

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16 FEB 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

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19 FEB 2021 00:01

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23 FEB 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

[Patient Cloud Close Date & Time](#)

02 MAR 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

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09 MAR 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

DAY 145

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

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

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

12 MAR 2021 00:01

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16 MAR 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

02 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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13 APR 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

[Patient Cloud Close Date & Time](#)

27 APR 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

DAY 194

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

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

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐ 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐ 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

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03 AUG 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐ 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐ 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐ 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐ 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐ 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐ 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐ 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

21 JAN 2022 00:01

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25 JAN 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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°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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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01 FEB 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

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04 FEB 2022 00:01

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08 FEB 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

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11 FEB 2022 00:01

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15 FEB 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

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US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐ 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

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01 MAR 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

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08 MAR 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

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US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

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22 MAR 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

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25 MAR 2022 00:01

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29 MAR 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

01 APR 2022 00:01

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05 APR 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

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12 APR 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

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19 APR 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

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26 APR 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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°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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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°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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐ 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐ 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐ 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐ 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐ 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

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29 JUL 2022 00:01

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02 AUG 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

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05 AUG 2022 00:01

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09 AUG 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

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12 AUG 2022 00:01

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16 AUG 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

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23 AUG 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

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30 AUG 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

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US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐ 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

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US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

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20 SEP 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

DAY 705

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

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27 SEP 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

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04 OCT 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐ 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

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11 OCT 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

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18 OCT 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐ 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

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US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐ 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐ 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

02 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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 ☐ 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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

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

[Patient Cloud Close Date & Time](#)

27 DEC 2022 23:59

US3402448

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:23:21

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

US3402448

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:23:21

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3402448

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:23:21

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

AEID	USA-US059-2020-MRNA-1273-P30 1000017
Adverse event	WORSENING OF EMPHYSEMA
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	09 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	11 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
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)	09 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	11 NOV 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	328 of 1665

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☒ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	SUBJECT WAS SENT HOME ON 2 LITERS OF CONTINUOUS OXYGEN
Narrative	AWAITING MEDICAL RECORDS
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:23:21

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

Yes ☒

No ☐

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

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:21

Name of Medication	CELEBREX
Prophylaxis	Yes ☐ No ☒
Indication	LEFT KNEE ARTHRITIS
Dose per administration	200
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:21

Name of Medication	ATORVASTATIN
Prophylaxis	Yes ☐ No ☒
Indication	HYPERCHOLESTERDEMIA
Dose per administration	40
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2006
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:21

Name of Medication	TOPIRAMATE
Prophylaxis	Yes ☐ No ☒
Indication	SCHIZOAFFECTIVE DISORDER
Dose per administration	50
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2012
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:21

Name of Medication	OLANZAPINE
Prophylaxis	Yes ☐ No ☒
Indication	SCHIZOAFFECTIVE DISORDER
Dose per administration	20
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2016
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:21

Name of Medication	OXYBUTININ
Prophylaxis	Yes ☐ No ☒
Indication	OVERACTIVE BLADDER
Dose per administration	10
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2012
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:21

Name of Medication	LOSARTAN POTASSIUM
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	100
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:21

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

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:21

Name of Medication	SERTRALINE
Prophylaxis	Yes ☐ No ☒
Indication	DEPRESSION
Dose per administration	40
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2016
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:21

Name of Medication	PANTOPRAZOLE
Prophylaxis	Yes ☐ No ☒
Indication	GASTROESOPHAGEAL REFLUX DISEASE
Dose per administration	40
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:21

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:21

Name of Medication	OXYGEN
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING OF EMPHYSEMA
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	LITERS
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	CONTINUOUSLY
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:21

	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	9 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3402448

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:23:21

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3402448

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:23:21

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

US3402448

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:23:21

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 ☐

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

SAEID	USA-US059-2020-MRNA-1273-P301000017
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:23:21

SAEID	USA-US059-2020-MRNA-1273-P301000017
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	17/NOV/2020 08:22
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

US3402448 (Prod: Meridian Clinical Research, LLC)

US3402448

Form: Participant Creation

Generated On: 26 Nov 2020 09:23:21

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3402448'	RWS_ENDPOINT ENDPOINT (b) (4) 	21 Oct 2020 21:08:26

US3402448

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 22:10:12

US3402448

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '21 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	21 Oct 2020 21:08:27

US3402448

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Oct 2020 22:10:12

US3402448

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:21

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	21 Oct 2020 22:10:12

US3402448

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:21

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1, the Birth Year is missing, however, the CRF has Year of Birth recorded as 1954. Please clarify the subject's Year of Birth and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 11:07:32
Query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1, the Birth Year is missing, however, the CRF has Year of Birth recorded as 1954. Please clarify the subject's Year of Birth and update as appropriate.' answered with 'PATIENTS DATE OF BIRTH IS 1954. THIS HAS ALREADY BEEN SENT BY OUR LAB TECH TO HAVE CORRECTED' (Site from DM).	Tammy Kohn (b) (4)	02 Nov 2020 12:46:01
User opened query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1, the Birth Year is missing, however, the CRF has Year of Birth recorded as 1954. Please clarify the subject's Year of Birth and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 17:25:24
User entered (b) (6) 1954'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 21:08:28

US3402448

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:21

[Age](#)

Audit	User	Time (GMT)
User entered '66'	(b) (4), (b) (6)	21 Oct 2020 22:10:32

US3402448

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:21

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	21 Oct 2020 22:10:32

US3402448

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:21

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '66'	System	21 Oct 2020 22:11:07
User entered empty.	System	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:21

Sex

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1 has no data recorded for the subject's sex, however, the CRF has Sex recorded as Female. Please clarify the subject's Sex and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 10:28:25
Query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1 has no data recorded for the subject's sex, however, the CRF has Sex recorded as Female. Please clarify the subject's Sex and update if appropriate.' answered with 'THIS PATIENT IS A FEMALE. THE LAB HAS ALREADY SENT THE INFORMATION TO HAVE IT CORRECTED ' (Site from DM).	Tammy Kohn (b) (4)	30 Oct 2020 19:55:20
User opened query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1 has no data recorded for the subject's sex, however, the CRF has Sex recorded as Female. Please clarify the subject's Sex and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 19:45:49
User entered 'Female (F)'	(b) (4), (b) (6)	21 Oct 2020 22:10:32

US3402448

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:21

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	21 Oct 2020 22:10:32

US3402448

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:21

[White](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	21 Oct 2020 22:10:32

US3402448

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:21

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 22:10:32

US3402448

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:21

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 22:10:32

US3402448

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:21

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 22:10:32

US3402448

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:21

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 22:10:32

US3402448

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:21

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 22:10:32

US3402448

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:21

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 22:10:32

US3402448

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:21

Unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 22:10:32

US3402448

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:21

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 22:10:32

US3402448

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:21

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 22:11:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 22:11:07
User entered '21 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 22:11:07
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 22:10:58
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'Oct 2020'	System	21 Oct 2020 22:11:07
User entered empty.	System	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '2020'	System	21 Oct 2020 22:11:07
User entered empty.	System	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:21

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 4 (4)'	(b) (4), (b) (6)	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:21

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:21

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:21

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:21

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	21 Oct 2020 21:08:27

US3402448

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:21

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 22:09:56

US3402448

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:23:21

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 22:56:57

US3402448

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Emphysema, LLT: Emphysema - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 22:59:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 22:59:43
Data point term sent to Coder	System	21 Oct 2020 22:58:16
User entered 'EMPHYSEMA'	Tammy Kohn (b) (4)	21 Oct 2020 22:57:23
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2016'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 22:57:23

US3402448

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 22:57:23

US3402448

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 23:13:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 23:13:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:13:34
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 22:57:23
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 22:57:23

US3402448

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 22:57:23

US3402448

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 22:57:23

US3402448

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	21 Oct 2020 22:57:23

US3402448

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '2016'	System	21 Oct 2020 22:57:23

US3402448

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 22:57:23

US3402448

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 22:57:23

US3402448

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 22:59:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 22:59:43
Data point term sent to Coder	System	21 Oct 2020 22:58:17
User entered 'HYPERCHOLESTERDEMIA'	Tammy Kohn (b) (4)	21 Oct 2020 22:58:04

US3402448

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2006'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 22:58:04

US3402448

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 22:58:04

US3402448

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 22:58:04

US3402448

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 22:58:04

US3402448

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 22:58:04

US3402448

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	21 Oct 2020 22:58:04

US3402448

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '2006'	System	21 Oct 2020 22:58:04

US3402448

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 22:58:04

US3402448

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 22:58:04

US3402448

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:21

[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)	21 Oct 2020 23:00:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 23:00:45
Data point term sent to Coder	System	21 Oct 2020 22:59:19
User entered 'DEPRESSION'	Tammy Kohn (b) (4)	21 Oct 2020 22:58:22
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 1998'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 22:58:22

US3402448

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 22:58:22

US3402448

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 22:58:22

US3402448

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 22:58:22

US3402448

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 22:58:22

US3402448

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	21 Oct 2020 22:58:22

US3402448

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '1998'	System	21 Oct 2020 22:58:22

US3402448

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 22:58:22

US3402448

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 22:58:22

US3402448

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Schizophrenia and other psychotic disorders, HLT: Schizoaffective and schizophreniform disorders, PT: Schizoaffective disorder, LLT: Schizoaffective disorder - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 23:01:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 23:01:48
Data point term sent to Coder	System	21 Oct 2020 23:00:22
User entered 'SCHIZOAFFECTIVE DISORDER'	Tammy Kohn (b) (4)	21 Oct 2020 23:00:12

US3402448

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:00:12

US3402448

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:00:12

US3402448

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:00:12

US3402448

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:00:12

US3402448

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:00:12

US3402448

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	21 Oct 2020 23:00:12

US3402448

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '2010'	System	21 Oct 2020 23:00:12

US3402448

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 23:00:12

US3402448

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 23:00:12

US3402448

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 23:02:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 23:02:35
Data point term sent to Coder	System	21 Oct 2020 23:01:23
User entered 'HYPERTENSION'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:00:38

US3402448

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2008'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:00:38

US3402448

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:00:38

US3402448

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:00:38

US3402448

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:00:38

US3402448

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:00:38

US3402448

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	21 Oct 2020 23:00:38

US3402448

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '2008'	System	21 Oct 2020 23:00:38

US3402448

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 23:00:38

US3402448

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 23:00:38

US3402448

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 23:02:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 23:02:35
Data point term sent to Coder	System	21 Oct 2020 23:01:23
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Tammy Kohn (b) (4)	21 Oct 2020 23:01:07

US3402448

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2006'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:01:07

US3402448

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:01:07

US3402448

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:01:07

US3402448

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:01:07

US3402448

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:01:07

US3402448

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	21 Oct 2020 23:01:07

US3402448

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '2006'	System	21 Oct 2020 23:01:07

US3402448

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 23:01:07

US3402448

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 23:01:07

US3402448

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Hiatal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 23:02:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 23:02:35
Data point term sent to Coder	System	21 Oct 2020 23:02:23
User entered 'HIATAL HERNIA'	Tammy Kohn (b) (4)	21 Oct 2020 23:01:39

US3402448

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'UN May 2020'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:01:39

US3402448

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:01:39

US3402448

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:01:39

US3402448

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:01:39

US3402448

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:01:39

US3402448

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'May 2020'	System	21 Oct 2020 23:01:39

US3402448

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '2020'	System	21 Oct 2020 23:01:39

US3402448

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 23:01:39

US3402448

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 23:01:39

US3402448

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Musculoskeletal and soft tissue investigations (excl enzyme tests), HLT: Musculoskeletal and soft tissue imaging procedures, PT: Arthroscopy, LLT: Arthroscopy L knee - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 23:02:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 23:02:36
Data point term sent to Coder	System	21 Oct 2020 23:02:23
User entered 'LEFT KNEE ARTHOSCOPY'	Tammy Kohn (b) (4)	21 Oct 2020 23:02:06

US3402448

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'UN Apr 2020'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:02:06

US3402448

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:02:06

US3402448

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:02:06

US3402448

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:02:06

US3402448

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:02:06

US3402448

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'Apr 2020'	System	21 Oct 2020 23:02:06

US3402448

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '2020'	System	21 Oct 2020 23:02:06

US3402448

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 23:02:06

US3402448

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 23:02:06

US3402448

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Knee arthritis - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 23:04:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 23:04:38
Data point term sent to Coder	System	21 Oct 2020 23:03:27
User entered 'LEFT KNEE ARTHRITIS'	Tammy Kohn (b) (4)	21 Oct 2020 23:02:37
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:02:37

US3402448

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:02:37

US3402448

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:02:37

US3402448

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:02:37

US3402448

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:02:37

US3402448

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	21 Oct 2020 23:02:37

US3402448

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '2018'	System	21 Oct 2020 23:02:37

US3402448

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 23:02:37

US3402448

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 23:02:37

US3402448

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Myoneurogenic bladder disorders, PT: Hypertonic bladder, LLT: Overactive bladder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 23:04:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 23:04:38
Data point term sent to Coder	System	21 Oct 2020 23:03:26
User entered 'OVERACTIVE BLADDER'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:02:58

US3402448

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2005'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:02:58

US3402448

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:02:58

US3402448

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:02:58

US3402448

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:02:58

US3402448

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:02:58

US3402448

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	21 Oct 2020 23:02:58

US3402448

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '2005'	System	21 Oct 2020 23:02:58

US3402448

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 23:02:58

US3402448

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 23:02:58

US3402448

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:23:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 23:04:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 23:04:37
Data point term sent to Coder	System	21 Oct 2020 23:03:28
User entered 'TOTAL HYSTERECTOMY'	Tammy Kohn (b) (4)	21 Oct 2020 23:03:24

US3402448

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2001'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:03:24

US3402448

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:23:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:03:24

US3402448

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:23:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:03:24

US3402448

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:03:24

US3402448

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:23:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:03:24

US3402448

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'Jan 2001'	System	21 Oct 2020 23:03:24

US3402448

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '2001'	System	21 Oct 2020 23:03:24

US3402448

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 23:03:24

US3402448

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 23:03:24

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:05:14

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:05:14

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '16:28'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:05:14

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '21 Oct 2020 16:28'	System	21 Oct 2020 23:05:14

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '157.5' cm	Tammy Kohn (b) (4)	21 Oct 2020 23:05:14
DataPoint set to visible.	(b) (4) System	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '84.4' kg	Tammy Kohn (b) (4)	21 Oct 2020 23:05:14
DataPoint set to visible.	(b) (4) System	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:21

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '34.02368'	System	21 Oct 2020 23:05:14
DataPoint set to visible.	System	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:21

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	21 Oct 2020 23:05:14
DataPoint set to visible.	System	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:05:14

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:05:14

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:05:14

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '74'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:05:14

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Oct 2020 23:05:14

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '18'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:05:14

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Oct 2020 23:05:14

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '128'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:05:14

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 23:05:14

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '80'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:05:14

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 23:05:14

US3402448

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:05:20

US3402448

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:05:20

US3402448

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:05:52

US3402448

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:21

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:05:52

US3402448

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:21

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User entered 'Surgically sterile (SURGICALLY STERILE)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:05:52

US3402448

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:21

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:05:52

US3402448

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2001'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:05:52

US3402448

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:21

Date of surgery unknown

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:05:52

US3402448

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:05:52

US3402448

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:21

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:05:52

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:21

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)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:21

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)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:21

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)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:21

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)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:21

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)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:21

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:21

[Specify](#)

Audit	User	Time (GMT)
User entered 'FREQUENTLY GOES TO STORES AND RESTAURANTS'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:21

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:21

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 '1'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:21

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'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:21

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:21

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 22:09:28

US3402448

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '21 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 22:09:28

US3402448

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Oct 2020 22:09:28

US3402448

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:21

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	21 Oct 2020 22:09:28

US3402448

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '21 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	21 Oct 2020 21:18:34

US3402448

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:21

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
User entered '187792'	RWS_ENDPOINT ENDPOINT (b) (4) 	21 Oct 2020 21:18:34

US3402448

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	21 Oct 2020 21:18:34

US3402448

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:21

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)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:08:50

US3402448

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:08:50

US3402448

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:08:50

US3402448

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:21

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:08:50

US3402448

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:21

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:08:50

US3402448

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4)	21 Oct 2020 23:08:50
DataPoint set to visible.	(b) (4) System	21 Oct 2020 22:10:58

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:21

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:21

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:21

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:21

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	22 Oct 2020 00:26:49
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	21 Oct 2020 23:11:26
User entered '16:28'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '21 Oct 2020 16:28'	System	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

Pulse (xxx)

Audit	User	Time (GMT)
User entered '74'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '18'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '128'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '80'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:21

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:21

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '18:02'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '21 Oct 2020 18:02'	System	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37.0' C	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '82'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '18'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '128'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '82'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:40

US3402448

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:40

US3402448

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 22:11:47

US3402448

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:21

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 22:11:47

US3402448

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:21

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)	21 Oct 2020 22:11:47

US3402448

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	21 Oct 2020 22:11:47

US3402448

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 22:11:47

US3402448

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '17:25' reason for change: Data Entry Error	Tammy Kohn (b) (4)	22 Oct 2020 00:26:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '15:25' reason for change: Data Entry Error	System	21 Oct 2020 22:12:01
User entered '15:25' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 22:12:01
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).		
User entered '15:' (non-conformant).	System	21 Oct 2020 22:11:47
	(b) (4), (b) (6)	21 Oct 2020 22:11:47

US3402448

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '21 Oct 2020 17:25'	System	22 Oct 2020 00:26:49
User entered '21 Oct 2020 15:25'	System	21 Oct 2020 22:12:01
User entered '21 Oct 2020 15:' (non-conformant).	System	21 Oct 2020 22:11:47

US3402448

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	21 Oct 2020 22:11:47

US3402448

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	21 Oct 2020 22:11:47

US3402448

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:21

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	21 Oct 2020 22:11:47

US3402448

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:12:12

US3402448

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:12:12

US3402448

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '18:02'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:12:12

US3402448

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '21 Oct 2020 18:02'	System	21 Oct 2020 23:12:12

US3402448

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:23:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:13:10

US3402448

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:21

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:13:10

US3402448

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:13:10

US3402448

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '17:10'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:13:10

US3402448

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '21 Oct 2020 17:10'	System	21 Oct 2020 23:13:10

US3402448

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:21

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:13:10

US3402448

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:13:10

US3402448

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:13:10

US3402448

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 23:13:10

US3402448

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:13:15

US3402448

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:23:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 23:13:15

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T18:13:21', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'df92be9e-cc17-4d33-85ff-cb4409eb605f'	System	21 Oct 2020 22:14:01
User entered 'Yes (Y)'	System	21 Oct 2020 22:14:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T18:13:32', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'df92be9e-cc17-4d33-85ff-cb4409eb605f'	System	21 Oct 2020 22:14:01
User entered '98.6'	System	21 Oct 2020 22:14:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T18:13:49', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'df92be9e-cc17-4d33-85ff-cb4409eb605f'	System	21 Oct 2020 22:14:01
User entered 'No (N)'	System	21 Oct 2020 22:14:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T18:13:58', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'df92be9e-cc17-4d33-85ff-cb4409eb605f' User entered '21 Oct 2020 18:13'	System	21 Oct 2020 22:14:01
	System	21 Oct 2020 22:14:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 15:45'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 18:15'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:12:25', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3f92f97a-3c6a-4b4c-bc1a-bc3aa0c2ff50'	System	22 Oct 2020 01:14:22
User entered 'Yes (Y)'	System	22 Oct 2020 01:14:22

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:12:38', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3f92f97a-3c6a-4b4c-bc1a-bc3aa0c2ff50'	System	22 Oct 2020 01:14:22
User entered '98.6'	System	22 Oct 2020 01:14:22

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:12:44', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3f92f97a-3c6a-4b4c-bc1a-bc3aa0c2ff50'	System	22 Oct 2020 01:14:22
User entered 'No (N)'	System	22 Oct 2020 01:14:22

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:14:19', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3f92f97a-3c6a-4b4c-bc1a-bc3aa0c2ff50'	System	22 Oct 2020 01:14:22
User entered '21 Oct 2020 21:14'	System	22 Oct 2020 01:14:22

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 21:10'	System	22 Oct 2020 00:26:49
User entered '21 Oct 2020 19:10'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 2'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:25:25', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '125ab44b-d2f4-483f-be43-76b259a67bc0'	System	22 Oct 2020 23:27:29
User entered 'Yes (Y)'	System	22 Oct 2020 23:27:29

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:25:41', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '125ab44b-d2f4-483f-be43-76b259a67bc0'	System	22 Oct 2020 23:27:29
User entered '98.9'	System	22 Oct 2020 23:27:29

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:25:46', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '125ab44b-d2f4-483f-be43-76b259a67bc0'	System	22 Oct 2020 23:27:29
User entered 'No (N)'	System	22 Oct 2020 23:27:29

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:27:26', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '125ab44b-d2f4-483f-be43-76b259a67bc0'	System	22 Oct 2020 23:27:29
User entered '22 Oct 2020 19:27'	System	22 Oct 2020 23:27:29

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 3'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:25:18', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'aa782f90-ccad-49ac-a7ed-21180d98ed69'	System	23 Oct 2020 17:26:30
User entered 'Yes (Y)'	System	23 Oct 2020 17:26:30

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:25:26', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'aa782f90-ccad-49ac-a7ed-21180d98ed69'	System	23 Oct 2020 17:26:30
User entered '99.4'	System	23 Oct 2020 17:26:30

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:25:32', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'aa782f90-ccad-49ac-a7ed-21180d98ed69'	System	23 Oct 2020 17:26:30
User entered 'No (N)'	System	23 Oct 2020 17:26:30

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:26:26', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'aa782f90-ccad-49ac-a7ed-21180d98ed69'	System	23 Oct 2020 17:26:30
User entered '23 Oct 2020 13:26'	System	23 Oct 2020 17:26:30

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 4'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:43:48', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'd86fb2bf-bfec-49d0-837d-7e8b02867661'	System	24 Oct 2020 20:44:23
User entered 'Yes (Y)'	System	24 Oct 2020 20:44:23

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:43:59', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'd86fb2bf-bfec-49d0-837d-7e8b02867661'	System	24 Oct 2020 20:44:23
User entered '98.4'	System	24 Oct 2020 20:44:23

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:44:03', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'd86fb2bf-bfec-49d0-837d-7e8b02867661'	System	24 Oct 2020 20:44:23
User entered 'No (N)'	System	24 Oct 2020 20:44:23

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:44:21', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'd86fb2bf-bfec-49d0-837d-7e8b02867661'	System	24 Oct 2020 20:44:23
User entered '24 Oct 2020 16:44'	System	24 Oct 2020 20:44:23

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 5'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:13:19', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'fbaab43c-bb61-4055-abfd-f5a9d90fd199'	System	25 Oct 2020 17:14:50
User entered 'Yes (Y)'	System	25 Oct 2020 17:14:50

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:13:30', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'fbaab43c-bb61-4055-abfd-f5a9d90fd199'	System	25 Oct 2020 17:14:50
User entered '98.0'	System	25 Oct 2020 17:14:50

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:13:35', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'fbaab43c-bb61-4055-abfd-f5a9d90fd199'	System	25 Oct 2020 17:14:50
User entered 'No (N)'	System	25 Oct 2020 17:14:50

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:14:47', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'fbaab43c-bb61-4055-abfd-f5a9d90fd199'	System	25 Oct 2020 17:14:50
User entered '25 Oct 2020 13:14'	System	25 Oct 2020 17:14:50

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 6'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:06:02', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e2709795-1236-455d-8f5e-0c29776c5894'	System	26 Oct 2020 20:06:39
User entered 'Yes (Y)'	System	26 Oct 2020 20:06:39

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:06:11', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e2709795-1236-455d-8f5e-0c29776c5894'	System	26 Oct 2020 20:06:39
User entered '98.5'	System	26 Oct 2020 20:06:39

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:06:15', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e2709795-1236-455d-8f5e-0c29776c5894'	System	26 Oct 2020 20:06:39
User entered 'No (N)'	System	26 Oct 2020 20:06:39

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:06:36', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e2709795-1236-455d-8f5e-0c29776c5894'	System	26 Oct 2020 20:06:39
User entered '26 Oct 2020 16:06'	System	26 Oct 2020 20:06:39

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 7'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:30:51', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '4cbdfb4e-c36b-4a3c-a8bd-164ad8eb3a4a'	System	27 Oct 2020 20:31:13
User entered 'Yes (Y)'	System	27 Oct 2020 20:31:13

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:31:01', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '4cbdfb4e-c36b-4a3c-a8bd-164ad8eb3a4a' User entered '98.2'	System	27 Oct 2020 20:31:13

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:31:05', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '4cbdfb4e-c36b-4a3c-a8bd-164ad8eb3a4a'	System	27 Oct 2020 20:31:13
User entered 'No (N)'	System	27 Oct 2020 20:31:13

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:31:11', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '4cbdfb4e-c36b-4a3c-a8bd-164ad8eb3a4a' User entered '27 Oct 2020 16:31'	System	27 Oct 2020 20:31:13
	System	27 Oct 2020 20:31:13

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-10-21T18:14:11', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '49f7b1bf-d32d-4fc0-8d86-7a2de19086a6'	System	21 Oct 2020 22:15:03
User entered 'None (1)'	System	21 Oct 2020 22:15:03

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T18:14:30', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '49f7b1bf-d32d-4fc0-8d86-7a2de19086a6'	System	21 Oct 2020 22:15:03
User entered 'No (N)'	System	21 Oct 2020 22:15:03

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T18:14:40', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '49f7b1bf-d32d-4fc0-8d86-7a2de19086a6'	System	21 Oct 2020 22:15:03
User entered 'No (N)'	System	21 Oct 2020 22:15:03

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-10-21T18:14:50', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '49f7b1bf-d32d-4fc0-8d86-7a2de19086a6'	System	21 Oct 2020 22:15:03
User entered 'None (1)'	System	21 Oct 2020 22:15:03

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T18:14:58', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '49f7b1bf-d32d-4fc0-8d86-7a2de19086a6'	System	21 Oct 2020 22:15:03
User entered '21 Oct 2020 18:14'	System	21 Oct 2020 22:15:03

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 15:45'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 18:15'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-10-21T21:14:44', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '285fb6c3-8c25-4b29-be90-8cf38b5616ed'	System	22 Oct 2020 01:15:27
User entered 'None (1)'	System	22 Oct 2020 01:15:27

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:14:49', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '285fb6c3-8c25-4b29-be90-8cf38b5616ed'	System	22 Oct 2020 01:15:27
User entered 'No (N)'	System	22 Oct 2020 01:15:27

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:14:57', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '285fb6c3-8c25-4b29-be90-8cf38b5616ed'	System	22 Oct 2020 01:15:27
User entered 'No (N)'	System	22 Oct 2020 01:15:27

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-10-21T21:15:11', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '285fb6c3-8c25-4b29-be90-8cf38b5616ed'	System	22 Oct 2020 01:15:27
User entered 'None (1)'	System	22 Oct 2020 01:15:27

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:15:21', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '285fb6c3-8c25-4b29-be90-8cf38b5616ed'	System	22 Oct 2020 01:15:27
User entered '21 Oct 2020 21:15'	System	22 Oct 2020 01:15:27

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 21:10'	System	22 Oct 2020 00:26:49
User entered '21 Oct 2020 19:10'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 2'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-10-22T19:27:35', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '20929518-aeec-4443-8d1a-3ad1d664685b'	System	22 Oct 2020 23:28:15
User entered 'None (1)'	System	22 Oct 2020 23:28:15

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:27:39', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '20929518-aeec-4443-8d1a-3ad1d664685b'	System	22 Oct 2020 23:28:15
User entered 'No (N)'	System	22 Oct 2020 23:28:15

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:27:50', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '20929518-aeec-4443-8d1a-3ad1d664685b'	System	22 Oct 2020 23:28:15
User entered 'No (N)'	System	22 Oct 2020 23:28:15

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-10-22T19:28:01', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '20929518-aeec-4443-8d1a-3ad1d664685b'	System	22 Oct 2020 23:28:15
User entered 'None (1)'	System	22 Oct 2020 23:28:15

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:28:12', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '20929518-aeec-4443-8d1a-3ad1d664685b'	System	22 Oct 2020 23:28:15
User entered '22 Oct 2020 19:28'	System	22 Oct 2020 23:28:15

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 3'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-10-23T13:26:37', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'cb7f71c1-2e45-47e8-a5eb-b33a1e1f9432'	System	23 Oct 2020 17:27:09
User entered 'None (1)'	System	23 Oct 2020 17:27:09

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:26:42', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'cb7f71c1-2e45-47e8-a5eb-b33a1e1f9432'	System	23 Oct 2020 17:27:09
User entered 'No (N)'	System	23 Oct 2020 17:27:09

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:26:47', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'cb7f71c1-2e45-47e8-a5eb-b33a1e1f9432'	System	23 Oct 2020 17:27:09
User entered 'No (N)'	System	23 Oct 2020 17:27:09

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-10-23T13:26:58', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'cb7f71c1-2e45-47e8-a5eb-b33a1e1f9432'	System	23 Oct 2020 17:27:09
User entered 'None (1)'	System	23 Oct 2020 17:27:09

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:27:06', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'cb7f71c1-2e45-47e8-a5eb-b33a1e1f9432'	System	23 Oct 2020 17:27:09
User entered '23 Oct 2020 13:27'	System	23 Oct 2020 17:27:09

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 4'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-10-24T16:44:33', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3f12a40b-731b-48de-be9b-3857c6cab8dd'	System	24 Oct 2020 20:45:31
User entered 'None (1)'	System	24 Oct 2020 20:45:31

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:44:49', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3f12a40b-731b-48de-be9b-3857c6cab8dd'	System	24 Oct 2020 20:45:31
User entered 'No (N)'	System	24 Oct 2020 20:45:31

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:45:12', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3f12a40b-731b-48de-be9b-3857c6cab8dd'	System	24 Oct 2020 20:45:31
User entered 'No (N)'	System	24 Oct 2020 20:45:31

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-10-24T16:45:21', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3f12a40b-731b-48de-be9b-3857c6cab8dd'	System	24 Oct 2020 20:45:31
User entered 'None (1)'	System	24 Oct 2020 20:45:31

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:45:28', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3f12a40b-731b-48de-be9b-3857c6cab8dd'	System	24 Oct 2020 20:45:31
User entered '24 Oct 2020 16:45'	System	24 Oct 2020 20:45:31

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 5'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-10-25T13:15:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0bc93bf7-a078-42e3-92bf-3903dbb2bf03'	System	25 Oct 2020 17:15:30
User entered 'None (1)'	System	25 Oct 2020 17:15:30

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:15:05', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0bc93bf7-a078-42e3-92bf-3903dbb2bf03'	System	25 Oct 2020 17:15:30
User entered 'No (N)'	System	25 Oct 2020 17:15:30

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:15:08', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0bc93bf7-a078-42e3-92bf-3903dbb2bf03'	System	25 Oct 2020 17:15:30
User entered 'No (N)'	System	25 Oct 2020 17:15:30

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-10-25T13:15:18', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0bc93bf7-a078-42e3-92bf-3903dbb2bf03'	System	25 Oct 2020 17:15:30
User entered 'None (1)'	System	25 Oct 2020 17:15:30

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:15:26', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0bc93bf7-a078-42e3-92bf-3903dbb2bf03'	System	25 Oct 2020 17:15:30
User entered '25 Oct 2020 13:15'	System	25 Oct 2020 17:15:30

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 6'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-10-26T16:06:50', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '38636184-92e1-4e63-b189-7f3f83cc2897'	System	26 Oct 2020 20:07:17
User entered 'None (1)'	System	26 Oct 2020 20:07:17

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:06:54', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '38636184-92e1-4e63-b189-7f3f83cc2897'	System	26 Oct 2020 20:07:17
User entered 'No (N)'	System	26 Oct 2020 20:07:17

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:06:58', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '38636184-92e1-4e63-b189-7f3f83cc2897'	System	26 Oct 2020 20:07:17
User entered 'No (N)'	System	26 Oct 2020 20:07:17

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-10-26T16:07:03', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '38636184-92e1-4e63-b189-7f3f83cc2897'	System	26 Oct 2020 20:07:17
User entered 'None (1)'	System	26 Oct 2020 20:07:17

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:07:12', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '38636184-92e1-4e63-b189-7f3f83cc2897'	System	26 Oct 2020 20:07:17
User entered '26 Oct 2020 16:07'	System	26 Oct 2020 20:07:17

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 7'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-10-27T16:31:17', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e96248ae-b7ee-4c15-86a2-e7515fc0b99f'	System	27 Oct 2020 20:32:15
User entered 'None (1)'	System	27 Oct 2020 20:32:15

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:31:20', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e96248ae-b7ee-4c15-86a2-e7515fc0b99f'	System	27 Oct 2020 20:32:15
User entered 'No (N)'	System	27 Oct 2020 20:32:15

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:31:41', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e96248ae-b7ee-4c15-86a2-e7515fc0b99f'	System	27 Oct 2020 20:32:15
User entered 'No (N)'	System	27 Oct 2020 20:32:15

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-10-27T16:31:50', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e96248ae-b7ee-4c15-86a2-e7515fc0b99f'	System	27 Oct 2020 20:32:15
User entered 'None (1)'	System	27 Oct 2020 20:32:15

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:31:56', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e96248ae-b7ee-4c15-86a2-e7515fc0b99f'	System	27 Oct 2020 20:32:15
User entered '27 Oct 2020 16:31'	System	27 Oct 2020 20:32:15

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 17:45'	System	22 Oct 2020 00:26:49
User entered '21 Oct 2020 15:45'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 20:15'	System	22 Oct 2020 00:26:49
User entered '21 Oct 2020 18:15'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:15:35', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'da685198-b910-4a5c-b154-e394b09747fa'	System	22 Oct 2020 01:16:52
User entered 'None (0)'	System	22 Oct 2020 01:16:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:16:06', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'da685198-b910-4a5c-b154-e394b09747fa'	System	22 Oct 2020 01:16:52
User entered 'None (0)'	System	22 Oct 2020 01:16:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:16:15', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'da685198-b910-4a5c-b154-e394b09747fa'	System	22 Oct 2020 01:16:52
User entered 'None (0)'	System	22 Oct 2020 01:16:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:16:19', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'da685198-b910-4a5c-b154-e394b09747fa'	System	22 Oct 2020 01:16:52
User entered 'None (0)'	System	22 Oct 2020 01:16:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:16:24', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'da685198-b910-4a5c-b154-e394b09747fa'	System	22 Oct 2020 01:16:52
User entered 'None (0)'	System	22 Oct 2020 01:16:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:16:28', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'da685198-b910-4a5c-b154-e394b09747fa'	System	22 Oct 2020 01:16:52
User entered 'None (0)'	System	22 Oct 2020 01:16:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-10-21T21:16:31', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'da685198-b910-4a5c-b154-e394b09747fa'	System	22 Oct 2020 01:16:52
User entered 'No (N)'	System	22 Oct 2020 01:16:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:16:48', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'da685198-b910-4a5c-b154-e394b09747fa'	System	22 Oct 2020 01:16:52
User entered '21 Oct 2020 21:16'	System	22 Oct 2020 01:16:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 21:10'	System	22 Oct 2020 00:26:49
User entered '21 Oct 2020 19:10'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:21

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 2'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:28:20', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e9098feb-4bdd-4dd6-bfdf-197dca036939'	System	22 Oct 2020 23:29:00
User entered 'None (0)'	System	22 Oct 2020 23:29:00

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:28:27', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e9098feb-4bdd-4dd6-bfdf-197dca036939'	System	22 Oct 2020 23:29:00
User entered 'None (0)'	System	22 Oct 2020 23:29:00

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:28:31', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e9098feb-4bdd-4dd6-bfdf-197dca036939'	System	22 Oct 2020 23:29:00
User entered 'None (0)'	System	22 Oct 2020 23:29:00

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:28:35', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e9098feb-4bdd-4dd6-bfdf-197dca036939'	System	22 Oct 2020 23:29:00
User entered 'None (0)'	System	22 Oct 2020 23:29:00

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:28:40', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e9098feb-4bdd-4dd6-bfdf-197dca036939'	System	22 Oct 2020 23:29:00
User entered 'None (0)'	System	22 Oct 2020 23:29:00

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:28:44', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e9098feb-4bdd-4dd6-bfdf-197dca036939'	System	22 Oct 2020 23:29:00
User entered 'None (0)'	System	22 Oct 2020 23:29:00

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-10-22T19:28:50', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e9098feb-4bdd-4dd6-bfdf-197dca036939'	System	22 Oct 2020 23:29:00
User entered 'No (N)'	System	22 Oct 2020 23:29:00

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:28:57', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e9098feb-4bdd-4dd6-bfdf-197dca036939'	System	22 Oct 2020 23:29:00
User entered '22 Oct 2020 19:28'	System	22 Oct 2020 23:29:00

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 3'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:27:14', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1747e839-6eb4-4f94-9e0c-9e7fb2240efc'	System	23 Oct 2020 17:27:52
User entered 'None (0)'	System	23 Oct 2020 17:27:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:27:19', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1747e839-6eb4-4f94-9e0c-9e7fb2240efc'	System	23 Oct 2020 17:27:52
User entered 'None (0)'	System	23 Oct 2020 17:27:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:27:23', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1747e839-6eb4-4f94-9e0c-9e7fb2240efc'	System	23 Oct 2020 17:27:52
User entered 'None (0)'	System	23 Oct 2020 17:27:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:27:28', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1747e839-6eb4-4f94-9e0c-9e7fb2240efc' User entered 'None (0)'	System	23 Oct 2020 17:27:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:27:31', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1747e839-6eb4-4f94-9e0c-9e7fb2240efc'	System	23 Oct 2020 17:27:52
User entered 'None (0)'	System	23 Oct 2020 17:27:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:27:35', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1747e839-6eb4-4f94-9e0c-9e7fb2240efc'	System	23 Oct 2020 17:27:52
User entered 'None (0)'	System	23 Oct 2020 17:27:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-10-23T13:27:40', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1747e839-6eb4-4f94-9e0c-9e7fb2240efc'	System	23 Oct 2020 17:27:52
User entered 'No (N)'	System	23 Oct 2020 17:27:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:27:48', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1747e839-6eb4-4f94-9e0c-9e7fb2240efc'	System	23 Oct 2020 17:27:52
User entered '23 Oct 2020 13:27'	System	23 Oct 2020 17:27:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 4'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:45:36', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '47c19f7e-9c17-4bb3-9306-66fe83fbada4'	System	24 Oct 2020 20:46:17
User entered 'None (0)'	System	24 Oct 2020 20:46:17

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:45:49', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '47c19f7e-9c17-4bb3-9306-66fe83fbada4'	System	24 Oct 2020 20:46:17
User entered 'No interference with activity (1)'	System	24 Oct 2020 20:46:17

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:45:53', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '47c19f7e-9c17-4bb3-9306-66fe83fbada4'	System	24 Oct 2020 20:46:17
User entered 'None (0)'	System	24 Oct 2020 20:46:17

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:45:57', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '47c19f7e-9c17-4bb3-9306-66fe83fbada4'	System	24 Oct 2020 20:46:17
User entered 'None (0)'	System	24 Oct 2020 20:46:17

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:46:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '47c19f7e-9c17-4bb3-9306-66fe83fbada4'	System	24 Oct 2020 20:46:17
User entered 'None (0)'	System	24 Oct 2020 20:46:17

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:46:02', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '47c19f7e-9c17-4bb3-9306-66fe83fbada4'	System	24 Oct 2020 20:46:17
User entered 'None (0)'	System	24 Oct 2020 20:46:17

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-10-24T16:46:05', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '47c19f7e-9c17-4bb3-9306-66fe83fbada4'	System	24 Oct 2020 20:46:17
User entered 'No (N)'	System	24 Oct 2020 20:46:17

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:46:14', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '47c19f7e-9c17-4bb3-9306-66fe83fbada4'	System	24 Oct 2020 20:46:17
User entered '24 Oct 2020 16:46'	System	24 Oct 2020 20:46:17

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 5'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:15:34', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e09af169-0646-4eeb-a467-35ab95cba33b'	System	25 Oct 2020 17:16:07
User entered 'None (0)'	System	25 Oct 2020 17:16:07

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:15:39', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e09af169-0646-4eeb-a467-35ab95cba33b'	System	25 Oct 2020 17:16:07
User entered 'None (0)'	System	25 Oct 2020 17:16:07

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:15:44', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e09af169-0646-4eeb-a467-35ab95cba33b'	System	25 Oct 2020 17:16:07
User entered 'None (0)'	System	25 Oct 2020 17:16:07

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:15:48', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e09af169-0646-4eeb-a467-35ab95cba33b'	System	25 Oct 2020 17:16:07
User entered 'None (0)'	System	25 Oct 2020 17:16:07

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:15:51', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e09af169-0646-4eeb-a467-35ab95cba33b'	System	25 Oct 2020 17:16:07
User entered 'None (0)'	System	25 Oct 2020 17:16:07

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:15:54', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e09af169-0646-4eeb-a467-35ab95cba33b'	System	25 Oct 2020 17:16:07
User entered 'None (0)'	System	25 Oct 2020 17:16:07

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-10-25T13:15:58', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e09af169-0646-4eeb-a467-35ab95cba33b'	System	25 Oct 2020 17:16:07
User entered 'No (N)'	System	25 Oct 2020 17:16:07

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:16:04', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e09af169-0646-4eeb-a467-35ab95cba33b'	System	25 Oct 2020 17:16:07
User entered '25 Oct 2020 13:16'	System	25 Oct 2020 17:16:07

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 6'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:07:17', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '676ffcbb-456e-420f-bb32-48df26aea730'	System	26 Oct 2020 20:07:50
User entered 'None (0)'	System	26 Oct 2020 20:07:50

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:07:22', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '676ffcbb-456e-420f-bb32-48df26aea730'	System	26 Oct 2020 20:07:50
User entered 'None (0)'	System	26 Oct 2020 20:07:50

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:07:27', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '676ffcbb-456e-420f-bb32-48df26aea730'	System	26 Oct 2020 20:07:50
User entered 'None (0)'	System	26 Oct 2020 20:07:50

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:07:33', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '676ffcbb-456e-420f-bb32-48df26aea730'	System	26 Oct 2020 20:07:50
User entered 'None (0)'	System	26 Oct 2020 20:07:50

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:07:36', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '676ffcbb-456e-420f-bb32-48df26aea730'	System	26 Oct 2020 20:07:50
User entered 'None (0)'	System	26 Oct 2020 20:07:50

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:07:39', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '676ffcbb-456e-420f-bb32-48df26aea730'	System	26 Oct 2020 20:07:50
User entered 'None (0)'	System	26 Oct 2020 20:07:50

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-10-26T16:07:43', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '676ffcbb-456e-420f-bb32-48df26aea730'	System	26 Oct 2020 20:07:50
User entered 'No (N)'	System	26 Oct 2020 20:07:50

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:07:47', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '676ffcbb-456e-420f-bb32-48df26aea730'	System	26 Oct 2020 20:07:50
User entered '26 Oct 2020 16:07'	System	26 Oct 2020 20:07:50

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 7'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:32:04', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '7215f7b5-3e2e-4bb0-a86a-b50d2aca8d84'	System	27 Oct 2020 20:32:57
User entered 'None (0)'	System	27 Oct 2020 20:32:57

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:32:08', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '7215f7b5-3e2e-4bb0-a86a-b50d2aca8d84'	System	27 Oct 2020 20:32:57
User entered 'None (0)'	System	27 Oct 2020 20:32:57

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:32:12', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '7215f7b5-3e2e-4bb0-a86a-b50d2aca8d84'	System	27 Oct 2020 20:32:57
User entered 'None (0)'	System	27 Oct 2020 20:32:57

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:32:18', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '7215f7b5-3e2e-4bb0-a86a-b50d2aca8d84'	System	27 Oct 2020 20:32:57
User entered 'None (0)'	System	27 Oct 2020 20:32:57

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:32:22', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '7215f7b5-3e2e-4bb0-a86a-b50d2aca8d84'	System	27 Oct 2020 20:32:57
User entered 'None (0)'	System	27 Oct 2020 20:32:57

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:32:26', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '7215f7b5-3e2e-4bb0-a86a-b50d2aca8d84'	System	27 Oct 2020 20:32:57
User entered 'None (0)'	System	27 Oct 2020 20:32:57

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-10-27T16:32:35', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '7215f7b5-3e2e-4bb0-a86a-b50d2aca8d84'	System	27 Oct 2020 20:32:57
User entered 'No (N)'	System	27 Oct 2020 20:32:57

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:32:39', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '7215f7b5-3e2e-4bb0-a86a-b50d2aca8d84'	System	27 Oct 2020 20:32:57
User entered '27 Oct 2020 16:32'	System	27 Oct 2020 20:32:57

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	29 Oct 2020 12:45:50

US3402448

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:21

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020'	Tammy Kohn (b) (4) (b) (4)	29 Oct 2020 12:45:50

US3402448

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4) (b) (4)	29 Oct 2020 12:45:50

US3402448

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	29 Oct 2020 12:45:50

US3402448

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	29 Oct 2020 12:45:54

US3402448

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 12:45:54

US3402448

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	04 Nov 2020 16:32:56

US3402448

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:21

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '4 Nov 2020'	Traci Hull (b) (4) (b) (4)	04 Nov 2020 16:32:56

US3402448

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	04 Nov 2020 16:32:56

US3402448

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Nov 2020 16:32:56

US3402448

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	04 Nov 2020 16:33:02

US3402448

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 16:33:02

US3402448

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 19:18:22

US3402448

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '11 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 19:18:22

US3402448

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	16 Nov 2020 19:18:22

US3402448

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	16 Nov 2020 19:18:48
User entered 'Could not reach subject.' reason for change: Per Query Resolution	(b) (4), (b) (6)	16 Nov 2020 19:18:48
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	16 Nov 2020 19:18:22
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 19:18:22

US3402448

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 19:18:54

US3402448

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 19:18:54

US3402448

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 19:48:56

US3402448

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 19:48:56

US3402448

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 19:48:56

US3402448

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:21

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	16 Nov 2020 19:48:56

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '13:03'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '16 Nov 2020 13:03'	System	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.4' C	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '79'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '14'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '127'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '84'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '14:11'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '16 Nov 2020 14:11'	System	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.7' C	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Pulse reported is out of range < 45 System or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		16 Nov 2020 20:13:03
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	16 Nov 2020 20:13:03
User entered '64' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:13:03
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Nov 2020 20:12:44
User entered '6'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '14'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '119'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '87'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:13:38

US3402448

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:13:38

US3402448

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 19:19:29

US3402448

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:21

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 19:19:29

US3402448

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:21

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)	16 Nov 2020 19:19:29

US3402448

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	16 Nov 2020 19:19:29

US3402448

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 19:19:29

US3402448

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '13:35'	(b) (4), (b) (6)	16 Nov 2020 19:19:29

US3402448

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '16 Nov 2020 13:35'	System	16 Nov 2020 19:19:29

US3402448

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	16 Nov 2020 19:19:29

US3402448

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	16 Nov 2020 19:19:29

US3402448

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:21

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	16 Nov 2020 19:19:29

US3402448

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:14:13

US3402448

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:14:13

US3402448

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '13:23'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:14:13

US3402448

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '16 Nov 2020 13:23'	System	16 Nov 2020 20:14:13

US3402448

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:23:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:14:26

US3402448

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:21

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:14:26

US3402448

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:14:26

US3402448

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '13:26'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:14:26

US3402448

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '16 Nov 2020 13:26'	System	16 Nov 2020 20:14:26

US3402448

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:21

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:14:26

US3402448

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:14:26

US3402448

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:14:26

US3402448

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 20:14:26

US3402448

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:14:31

US3402448

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 20:14:31

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:20:53', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '188e71a6-903d-47ba-992e-30d26b6fca6b'	System	16 Nov 2020 19:21:25
User entered 'Yes (Y)'	System	16 Nov 2020 19:21:25

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:21:04', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '188e71a6-903d-47ba-992e-30d26b6fca6b'	System	16 Nov 2020 19:21:25
User entered '98.0'	System	16 Nov 2020 19:21:25

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:21:12', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '188e71a6-903d-47ba-992e-30d26b6fca6b'	System	16 Nov 2020 19:21:25
User entered 'No (N)'	System	16 Nov 2020 19:21:25

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:21:20', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '188e71a6-903d-47ba-992e-30d26b6fca6b' User entered '16 Nov 2020 14:21'	System	16 Nov 2020 19:21:25
	System	16 Nov 2020 19:21:25

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020 13:55'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020 16:25'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 1, after vaccination (at home)'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:51:15', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0e8c56a4-507d-4626-ab51-27a0a87565e2'	System	17 Nov 2020 09:51:44
User entered 'Yes (Y)'	System	17 Nov 2020 09:51:44

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:51:30', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0e8c56a4-507d-4626-ab51-27a0a87565e2'	System	17 Nov 2020 09:51:44
User entered '98.0'	System	17 Nov 2020 09:51:44

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:51:35', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0e8c56a4-507d-4626-ab51-27a0a87565e2'	System	17 Nov 2020 09:51:44
User entered 'No (N)'	System	17 Nov 2020 09:51:44

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:51:40', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0e8c56a4-507d-4626-ab51-27a0a87565e2'	System	17 Nov 2020 09:51:44
User entered '17 Nov 2020 04:51'	System	17 Nov 2020 09:51:44

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020 17:20'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 2'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:15:41', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '13b5452b-2fb9-40c8-a20d-4c4c4d139ceb'	System	17 Nov 2020 20:16:12
User entered 'Yes (Y)'	System	17 Nov 2020 20:16:12

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:15:54', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '13b5452b-2fb9-40c8-a20d-4c4c4d139ceb'	System	17 Nov 2020 20:16:12
User entered '98.4'	System	17 Nov 2020 20:16:12

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:15:58', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '13b5452b-2fb9-40c8-a20d-4c4c4d139ceb'	System	17 Nov 2020 20:16:12
User entered 'No (N)'	System	17 Nov 2020 20:16:12

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:16:09', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '13b5452b-2fb9-40c8-a20d-4c4c4d139ceb'	System	17 Nov 2020 20:16:12
User entered '17 Nov 2020 15:16'	System	17 Nov 2020 20:16:12

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 3'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:42:48', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0962b1ff-d856-410f-ba5b-e611fb486dfb'	System	18 Nov 2020 21:43:23
User entered 'Yes (Y)'	System	18 Nov 2020 21:43:23

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:42:55', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0962b1ff-d856-410f-ba5b-e611fb486dfb'	System	18 Nov 2020 21:43:23
User entered '99.2'	System	18 Nov 2020 21:43:23

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:43:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0962b1ff-d856-410f-ba5b-e611fb486dfb'	System	18 Nov 2020 21:43:23
User entered 'No (N)'	System	18 Nov 2020 21:43:23

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:43:20', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0962b1ff-d856-410f-ba5b-e611fb486dfb'	System	18 Nov 2020 21:43:23
User entered '18 Nov 2020 16:43'	System	18 Nov 2020 21:43:23

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 4'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:13:08', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'd1997dcb-d92a-4e37-a267-cb65d902f912'	System	19 Nov 2020 21:13:41
User entered 'Yes (Y)'	System	19 Nov 2020 21:13:41

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:13:16', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'd1997dcb-d92a-4e37-a267-cb65d902f912'	System	19 Nov 2020 21:13:41
User entered '98.7'	System	19 Nov 2020 21:13:41

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:13:21', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'd1997dcb-d92a-4e37-a267-cb65d902f912'	System	19 Nov 2020 21:13:41
User entered 'No (N)'	System	19 Nov 2020 21:13:41

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:13:34', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'd1997dcb-d92a-4e37-a267-cb65d902f912'	System	19 Nov 2020 21:13:41
User entered '19 Nov 2020 16:13'	System	19 Nov 2020 21:13:41

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 5'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:17:46', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'b19f6219-9fc0-4ccd-92b9-f7e207cdd382'	System	20 Nov 2020 22:18:40
User entered 'Yes (Y)'	System	20 Nov 2020 22:18:40

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:18:20', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'b19f6219-9fc0-4ccd-92b9-f7e207cdd382'	System	20 Nov 2020 22:18:40
User entered '98.2'	System	20 Nov 2020 22:18:40

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:18:29', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'b19f6219-9fc0-4ccd-92b9-f7e207cdd382'	System	20 Nov 2020 22:18:40
User entered 'No (N)'	System	20 Nov 2020 22:18:40

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:18:38', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'b19f6219-9fc0-4ccd-92b9-f7e207cdd382'	System	20 Nov 2020 22:18:40
User entered '20 Nov 2020 17:18'	System	20 Nov 2020 22:18:40

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 6'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:03:28', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '90b6d767-0d33-43cc-b1a7-677126d292fe'	System	21 Nov 2020 17:03:57
User entered 'Yes (Y)'	System	21 Nov 2020 17:03:57

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:03:43', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '90b6d767-0d33-43cc-b1a7-677126d292fe'	System	21 Nov 2020 17:03:57
User entered '98.8'	System	21 Nov 2020 17:03:57

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:03:49', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '90b6d767-0d33-43cc-b1a7-677126d292fe'	System	21 Nov 2020 17:03:57
User entered 'No (N)'	System	21 Nov 2020 17:03:57

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:03:53', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '90b6d767-0d33-43cc-b1a7-677126d292fe'	System	21 Nov 2020 17:03:57
User entered '21 Nov 2020 12:03'	System	21 Nov 2020 17:03:57

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 7'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:56:11', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '4e591ada-ecb3-4810-9cc8-65845face6af'	System	23 Nov 2020 13:56:42
User entered 'Yes (Y)'	System	23 Nov 2020 13:56:42

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:56:29', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '4e591ada-ecb3-4810-9cc8-65845face6af'	System	23 Nov 2020 13:56:42
User entered '98.7'	System	23 Nov 2020 13:56:42

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:56:33', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '4e591ada-ecb3-4810-9cc8-65845face6af'	System	23 Nov 2020 13:56:42
User entered 'No (N)'	System	23 Nov 2020 13:56:42

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:56:39', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '4e591ada-ecb3-4810-9cc8-65845face6af'	System	23 Nov 2020 13:56:42
User entered '23 Nov 2020 08:56'	System	23 Nov 2020 13:56:42

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-11-16T14:21:33', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '5cb9312e-4d63-487c-9077-3f21d93ae309'	System	16 Nov 2020 19:22:25
User entered 'None (1)'	System	16 Nov 2020 19:22:25

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:21:54', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '5cb9312e-4d63-487c-9077-3f21d93ae309'	System	16 Nov 2020 19:22:25
User entered 'No (N)'	System	16 Nov 2020 19:22:25

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:22:03', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '5cb9312e-4d63-487c-9077-3f21d93ae309'	System	16 Nov 2020 19:22:25
User entered 'No (N)'	System	16 Nov 2020 19:22:25

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-11-16T14:22:11', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '5cb9312e-4d63-487c-9077-3f21d93ae309'	System	16 Nov 2020 19:22:25
User entered 'None (1)'	System	16 Nov 2020 19:22:25

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:22:21', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '5cb9312e-4d63-487c-9077-3f21d93ae309'	System	16 Nov 2020 19:22:25
User entered '16 Nov 2020 14:22'	System	16 Nov 2020 19:22:25

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020 13:55'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020 16:25'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 1, after vaccination (at home)'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-11-17T04:51:46', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'bc79eb27-e1ed-4fc5-8495-09804d5f237f'	System	17 Nov 2020 09:52:13
User entered 'None (1)'	System	17 Nov 2020 09:52:13

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:51:51', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'bc79eb27-e1ed-4fc5-8495-09804d5f237f'	System	17 Nov 2020 09:52:13
User entered 'No (N)'	System	17 Nov 2020 09:52:13

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:51:58', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'bc79eb27-e1ed-4fc5-8495-09804d5f237f'	System	17 Nov 2020 09:52:13
User entered 'No (N)'	System	17 Nov 2020 09:52:13

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-11-17T04:52:03', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'bc79eb27-e1ed-4fc5-8495-09804d5f237f'	System	17 Nov 2020 09:52:13
User entered 'None (1)'	System	17 Nov 2020 09:52:13

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:52:10', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'bc79eb27-e1ed-4fc5-8495-09804d5f237f' User entered '17 Nov 2020 04:52'	System	17 Nov 2020 09:52:13

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020 17:20'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 2'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-11-17T15:16:16', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '4ad0cdc0-7f3a-4fee-9e83-186caa83b790'	System	17 Nov 2020 20:16:52
User entered 'None (1)'	System	17 Nov 2020 20:16:52

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:16:22', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '4ad0cdc0-7f3a-4fee-9e83-186caa83b790'	System	17 Nov 2020 20:16:52
User entered 'No (N)'	System	17 Nov 2020 20:16:52

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:16:33', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '4ad0cdc0-7f3a-4fee-9e83-186caa83b790'	System	17 Nov 2020 20:16:52
User entered 'No (N)'	System	17 Nov 2020 20:16:52

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-11-17T15:16:41', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '4ad0cdc0-7f3a-4fee-9e83-186caa83b790'	System	17 Nov 2020 20:16:52
User entered 'None (1)'	System	17 Nov 2020 20:16:52

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:16:48', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '4ad0cdc0-7f3a-4fee-9e83-186caa83b790'	System	17 Nov 2020 20:16:52
User entered '17 Nov 2020 15:16'	System	17 Nov 2020 20:16:52

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 3'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-11-18T16:43:32', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '2f000858-cbd7-471b-94f7-bc4b5a16da58'	System	18 Nov 2020 21:43:57
User entered 'None (1)'	System	18 Nov 2020 21:43:57

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:43:37', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '2f000858-cbd7-471b-94f7-bc4b5a16da58'	System	18 Nov 2020 21:43:57
User entered 'No (N)'	System	18 Nov 2020 21:43:57

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:43:41', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '2f000858-cbd7-471b-94f7-bc4b5a16da58'	System	18 Nov 2020 21:43:57
User entered 'No (N)'	System	18 Nov 2020 21:43:57

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-11-18T16:43:44', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '2f000858-cbd7-471b-94f7-bc4b5a16da58'	System	18 Nov 2020 21:43:57
User entered 'None (1)'	System	18 Nov 2020 21:43:57

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:43:51', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '2f000858-cbd7-471b-94f7-bc4b5a16da58'	System	18 Nov 2020 21:43:57
User entered '18 Nov 2020 16:43'	System	18 Nov 2020 21:43:57

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 4'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-11-19T16:13:43', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3b9c4f88-d4fe-4848-861c-fe3d07d3ce89'	System	19 Nov 2020 21:14:19
User entered 'None (1)'	System	19 Nov 2020 21:14:19

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:13:48', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3b9c4f88-d4fe-4848-861c-fe3d07d3ce89'	System	19 Nov 2020 21:14:19
User entered 'No (N)'	System	19 Nov 2020 21:14:19

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:13:51', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3b9c4f88-d4fe-4848-861c-fe3d07d3ce89'	System	19 Nov 2020 21:14:19
User entered 'No (N)'	System	19 Nov 2020 21:14:19

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-11-19T16:14:01', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3b9c4f88-d4fe-4848-861c-fe3d07d3ce89'	System	19 Nov 2020 21:14:19
User entered 'None (1)'	System	19 Nov 2020 21:14:19

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:14:09', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3b9c4f88-d4fe-4848-861c-fe3d07d3ce89'	System	19 Nov 2020 21:14:19
User entered '19 Nov 2020 16:14'	System	19 Nov 2020 21:14:19

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 5'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:21

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 (f1b8aa5a37a01477)', Time: '2020-11-20T17:18:45', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '33660401-c153-4678-afab-849747a1d5be'	System	20 Nov 2020 22:19:14
User entered 'None (1)'	System	20 Nov 2020 22:19:14

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:18:50', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '33660401-c153-4678-afab-849747a1d5be'	System	20 Nov 2020 22:19:14
User entered 'No (N)'	System	20 Nov 2020 22:19:14

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:19:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '33660401-c153-4678-afab-849747a1d5be'	System	20 Nov 2020 22:19:14
User entered 'No (N)'	System	20 Nov 2020 22:19:14

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:21

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 (f1b8aa5a37a01477)', Time: '2020-11-20T17:19:03', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '33660401-c153-4678-afab-849747a1d5be'	System	20 Nov 2020 22:19:14
User entered 'None (1)'	System	20 Nov 2020 22:19:14

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:19:09', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '33660401-c153-4678-afab-849747a1d5be'	System	20 Nov 2020 22:19:14
User entered '20 Nov 2020 17:19'	System	20 Nov 2020 22:19:14

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 6'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:21

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 (f1b8aa5a37a01477)', Time: '2020-11-21T12:04:15', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '6c9d1dc4-bc67-4936-85c8-7e3b7b671dfb'	System	21 Nov 2020 17:04:37
User entered 'None (1)'	System	21 Nov 2020 17:04:37

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:04:20', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '6c9d1dc4-bc67-4936-85c8-7e3b7b671dfb'	System	21 Nov 2020 17:04:37
User entered 'No (N)'	System	21 Nov 2020 17:04:37

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:04:24', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '6c9d1dc4-bc67-4936-85c8-7e3b7b671dfb'	System	21 Nov 2020 17:04:37
User entered 'No (N)'	System	21 Nov 2020 17:04:37

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:21

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 (f1b8aa5a37a01477)', Time: '2020-11-21T12:04:28', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '6c9d1dc4-bc67-4936-85c8-7e3b7b671dfb'	System	21 Nov 2020 17:04:37
User entered 'None (1)'	System	21 Nov 2020 17:04:37

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:04:32', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '6c9d1dc4-bc67-4936-85c8-7e3b7b671dfb'	System	21 Nov 2020 17:04:37
User entered '21 Nov 2020 12:04'	System	21 Nov 2020 17:04:37

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 7'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:21

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 (f1b8aa5a37a01477)', Time: '2020-11-23T08:56:47', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e5dbe9c8-c192-42b1-a051-eb0051b3d82f'	System	23 Nov 2020 13:57:28
User entered 'None (1)'	System	23 Nov 2020 13:57:28

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:57:12', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e5dbe9c8-c192-42b1-a051-eb0051b3d82f'	System	23 Nov 2020 13:57:28
User entered 'No (N)'	System	23 Nov 2020 13:57:28

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:57:16', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e5dbe9c8-c192-42b1-a051-eb0051b3d82f'	System	23 Nov 2020 13:57:28
User entered 'No (N)'	System	23 Nov 2020 13:57:28

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:21

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 (f1b8aa5a37a01477)', Time: '2020-11-23T08:57:19', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e5dbe9c8-c192-42b1-a051-eb0051b3d82f'	System	23 Nov 2020 13:57:28
User entered 'None (1)'	System	23 Nov 2020 13:57:28

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:57:24', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e5dbe9c8-c192-42b1-a051-eb0051b3d82f' User entered '23 Nov 2020 08:57'	System	23 Nov 2020 13:57:28
	System	23 Nov 2020 13:57:28

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:22:30', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '8cace60c-7dd3-49b7-9cc6-9cad16953b5f'	System	16 Nov 2020 19:22:58
User entered 'None (0)'	System	16 Nov 2020 19:22:58

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:22:34', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '8cace60c-7dd3-49b7-9cc6-9cad16953b5f'	System	16 Nov 2020 19:22:58
User entered 'None (0)'	System	16 Nov 2020 19:22:58

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:22:37', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '8cace60c-7dd3-49b7-9cc6-9cad16953b5f'	System	16 Nov 2020 19:22:58
User entered 'None (0)'	System	16 Nov 2020 19:22:58

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:22:40', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '8cace60c-7dd3-49b7-9cc6-9cad16953b5f'	System	16 Nov 2020 19:22:58
User entered 'None (0)'	System	16 Nov 2020 19:22:58

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:22:43', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '8cace60c-7dd3-49b7-9cc6-9cad16953b5f'	System	16 Nov 2020 19:22:58
User entered 'None (0)'	System	16 Nov 2020 19:22:58

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:22:46', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '8cace60c-7dd3-49b7-9cc6-9cad16953b5f'	System	16 Nov 2020 19:22:58
User entered 'None (0)'	System	16 Nov 2020 19:22:58

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-11-16T14:22:50', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '8cace60c-7dd3-49b7-9cc6-9cad16953b5f'	System	16 Nov 2020 19:22:58
User entered 'No (N)'	System	16 Nov 2020 19:22:58

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:22:55', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '8cace60c-7dd3-49b7-9cc6-9cad16953b5f' User entered '16 Nov 2020 14:22'	System	16 Nov 2020 19:22:58
	System	16 Nov 2020 19:22:58

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020 13:55'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020 16:25'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 1, after vaccination (at home)'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:52:44', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'bd139641-3ef0-4ee2-8763-44eeeb507373'	System	17 Nov 2020 09:53:14
User entered 'None (0)'	System	17 Nov 2020 09:53:14

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:52:48', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'bd139641-3ef0-4ee2-8763-44eeeb507373'	System	17 Nov 2020 09:53:14
User entered 'None (0)'	System	17 Nov 2020 09:53:14

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:52:51', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'bd139641-3ef0-4ee2-8763-44eeeb507373'	System	17 Nov 2020 09:53:14
User entered 'None (0)'	System	17 Nov 2020 09:53:14

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:52:54', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'bd139641-3ef0-4ee2-8763-44eeeb507373'	System	17 Nov 2020 09:53:14
User entered 'None (0)'	System	17 Nov 2020 09:53:14

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:52:57', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'bd139641-3ef0-4ee2-8763-44eeeb507373'	System	17 Nov 2020 09:53:14
User entered 'None (0)'	System	17 Nov 2020 09:53:14

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:53:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'bd139641-3ef0-4ee2-8763-44ee2b507373'	System	17 Nov 2020 09:53:14
User entered 'None (0)'	System	17 Nov 2020 09:53:14

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-11-17T04:53:05', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'bd139641-3ef0-4ee2-8763-44eeeb507373'	System	17 Nov 2020 09:53:14
User entered 'No (N)'	System	17 Nov 2020 09:53:14

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:53:09', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'bd139641-3ef0-4ee2-8763-44eeeb507373'	System	17 Nov 2020 09:53:14
User entered '17 Nov 2020 04:53'	System	17 Nov 2020 09:53:14

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020 17:20'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 2'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:16:55', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a0b20f8d-b682-415c-8f89-1f66cc2f7586'	System	17 Nov 2020 20:17:43
User entered 'None (0)'	System	17 Nov 2020 20:17:43

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:17:03', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a0b20f8d-b682-415c-8f89-1f66cc2f7586'	System	17 Nov 2020 20:17:43
User entered 'None (0)'	System	17 Nov 2020 20:17:43

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:17:08', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a0b20f8d-b682-415c-8f89-1f66cc2f7586'	System	17 Nov 2020 20:17:43
User entered 'None (0)'	System	17 Nov 2020 20:17:43

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:17:11', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a0b20f8d-b682-415c-8f89-1f66cc2f7586'	System	17 Nov 2020 20:17:43
User entered 'None (0)'	System	17 Nov 2020 20:17:43

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:17:15', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a0b20f8d-b682-415c-8f89-1f66cc2f7586'	System	17 Nov 2020 20:17:43
User entered 'None (0)'	System	17 Nov 2020 20:17:43

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:17:19', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a0b20f8d-b682-415c-8f89-1f66cc2f7586'	System	17 Nov 2020 20:17:43
User entered 'None (0)'	System	17 Nov 2020 20:17:43

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-11-17T15:17:24', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a0b20f8d-b682-415c-8f89-1f66cc2f7586'	System	17 Nov 2020 20:17:43
User entered 'No (N)'	System	17 Nov 2020 20:17:43

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:17:37', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a0b20f8d-b682-415c-8f89-1f66cc2f7586'	System	17 Nov 2020 20:17:43
User entered '17 Nov 2020 15:17'	System	17 Nov 2020 20:17:43

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 3'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:44:01', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1a5c2a3b-e044-4f73-97b9-f738bab0cd5a'	System	18 Nov 2020 21:44:42
User entered 'None (0)'	System	18 Nov 2020 21:44:42

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:44:05', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1a5c2a3b-e044-4f73-97b9-f738bab0cd5a'	System	18 Nov 2020 21:44:42
User entered 'None (0)'	System	18 Nov 2020 21:44:42

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:44:09', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1a5c2a3b-e044-4f73-97b9-f738bab0cd5a'	System	18 Nov 2020 21:44:42
User entered 'None (0)'	System	18 Nov 2020 21:44:42

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:44:14', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1a5c2a3b-e044-4f73-97b9-f738bab0cd5a'	System	18 Nov 2020 21:44:42
User entered 'None (0)'	System	18 Nov 2020 21:44:42

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:44:18', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1a5c2a3b-e044-4f73-97b9-f738bab0cd5a'	System	18 Nov 2020 21:44:42
User entered 'None (0)'	System	18 Nov 2020 21:44:42

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:44:22', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1a5c2a3b-e044-4f73-97b9-f738bab0cd5a'	System	18 Nov 2020 21:44:42
User entered 'None (0)'	System	18 Nov 2020 21:44:42

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-11-18T16:44:32', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1a5c2a3b-e044-4f73-97b9-f738bab0cd5a'	System	18 Nov 2020 21:44:42
User entered 'No (N)'	System	18 Nov 2020 21:44:42

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:44:37', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1a5c2a3b-e044-4f73-97b9-f738bab0cd5a'	System	18 Nov 2020 21:44:42
User entered '18 Nov 2020 16:44'	System	18 Nov 2020 21:44:42

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 4'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:14:19', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a956fece-3c6c-4cef-9da7-b739b3a5ca39'	System	19 Nov 2020 21:15:09
User entered 'None (0)'	System	19 Nov 2020 21:15:09

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:14:34', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a956fece-3c6c-4cef-9da7-b739b3a5ca39'	System	19 Nov 2020 21:15:09
User entered 'None (0)'	System	19 Nov 2020 21:15:09

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:14:39', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a956fece-3c6c-4cef-9da7-b739b3a5ca39'	System	19 Nov 2020 21:15:09
User entered 'None (0)'	System	19 Nov 2020 21:15:09

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:14:44', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a956fece-3c6c-4cef-9da7-b739b3a5ca39'	System	19 Nov 2020 21:15:09
User entered 'None (0)'	System	19 Nov 2020 21:15:09

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:14:48', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a956fece-3c6c-4cef-9da7-b739b3a5ca39'	System	19 Nov 2020 21:15:09
User entered 'None (0)'	System	19 Nov 2020 21:15:09

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:14:52', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a956fece-3c6c-4cef-9da7-b739b3a5ca39'	System	19 Nov 2020 21:15:09
User entered 'None (0)'	System	19 Nov 2020 21:15:09

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:21

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 (45159e7f9db483f7)', Time: '2020-11-19T16:14:57', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a956fece-3c6c-4cef-9da7-b739b3a5ca39'	System	19 Nov 2020 21:15:09
User entered 'No (N)'	System	19 Nov 2020 21:15:09

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:15:02', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a956fece-3c6c-4cef-9da7-b739b3a5ca39'	System	19 Nov 2020 21:15:09
User entered '19 Nov 2020 16:15'	System	19 Nov 2020 21:15:09

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 5'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:19:18', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'ee8e336f-c342-498e-8824-ca23b32afccb'	System	20 Nov 2020 22:20:35
User entered 'None (0)'	System	20 Nov 2020 22:20:35

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:19:33', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'ee8e336f-c342-498e-8824-ca23b32afccb'	System	20 Nov 2020 22:20:35
User entered 'None (0)'	System	20 Nov 2020 22:20:35

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:19:38', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'ee8e336f-c342-498e-8824-ca23b32afccb'	System	20 Nov 2020 22:20:35
User entered 'None (0)'	System	20 Nov 2020 22:20:35

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:19:42', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'ee8e336f-c342-498e-8824-ca23b32afccb'	System	20 Nov 2020 22:20:35
User entered 'None (0)'	System	20 Nov 2020 22:20:35

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:19:45', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'ee8e336f-c342-498e-8824-ca23b32afccb'	System	20 Nov 2020 22:20:35
User entered 'None (0)'	System	20 Nov 2020 22:20:35

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:19:49', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'ee8e336f-c342-498e-8824-ca23b32afccb'	System	20 Nov 2020 22:20:35
User entered 'None (0)'	System	20 Nov 2020 22:20:35

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:21

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 (f1b8aa5a37a01477)', Time: '2020-11-20T17:20:24', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'ee8e336f-c342-498e-8824-ca23b32afccb'	System	20 Nov 2020 22:20:35
User entered 'No (N)'	System	20 Nov 2020 22:20:35

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:20:29', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'ee8e336f-c342-498e-8824-ca23b32afccb'	System	20 Nov 2020 22:20:35
User entered '20 Nov 2020 17:20'	System	20 Nov 2020 22:20:35

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 6'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:04:38', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'afd1da54-4141-4dfb-9d1a-dac93a7a60c7'	System	21 Nov 2020 17:05:11
User entered 'None (0)'	System	21 Nov 2020 17:05:11

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:04:41', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'afd1da54-4141-4dfb-9d1a-dac93a7a60c7'	System	21 Nov 2020 17:05:11
User entered 'None (0)'	System	21 Nov 2020 17:05:11

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:04:44', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'afd1da54-4141-4dfb-9d1a-dac93a7a60c7'	System	21 Nov 2020 17:05:11
User entered 'None (0)'	System	21 Nov 2020 17:05:11

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:04:47', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'afd1da54-4141-4dfb-9d1a-dac93a7a60c7'	System	21 Nov 2020 17:05:11
User entered 'None (0)'	System	21 Nov 2020 17:05:11

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:04:50', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'afd1da54-4141-4dfb-9d1a-dac93a7a60c7'	System	21 Nov 2020 17:05:11
User entered 'None (0)'	System	21 Nov 2020 17:05:11

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:04:53', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'afd1da54-4141-4dfb-9d1a-dac93a7a60c7'	System	21 Nov 2020 17:05:11
User entered 'None (0)'	System	21 Nov 2020 17:05:11

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:21

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 (f1b8aa5a37a01477)', Time: '2020-11-21T12:05:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'afd1da54-4141-4dfb-9d1a-dac93a7a60c7'	System	21 Nov 2020 17:05:11
User entered 'No (N)'	System	21 Nov 2020 17:05:11

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:05:07', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'afd1da54-4141-4dfb-9d1a-dac93a7a60c7'	System	21 Nov 2020 17:05:11
User entered '21 Nov 2020 12:05'	System	21 Nov 2020 17:05:11

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 7'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:57:29', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '9c676010-bf93-4df2-b116-6de3e91d8953'	System	23 Nov 2020 13:58:05
User entered 'None (0)'	System	23 Nov 2020 13:58:05

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:57:33', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '9c676010-bf93-4df2-b116-6de3e91d8953'	System	23 Nov 2020 13:58:05
User entered 'None (0)'	System	23 Nov 2020 13:58:05

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:57:36', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '9c676010-bf93-4df2-b116-6de3e91d8953'	System	23 Nov 2020 13:58:05
User entered 'None (0)'	System	23 Nov 2020 13:58:05

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:57:39', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '9c676010-bf93-4df2-b116-6de3e91d8953'	System	23 Nov 2020 13:58:05
User entered 'None (0)'	System	23 Nov 2020 13:58:05

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:57:42', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '9c676010-bf93-4df2-b116-6de3e91d8953'	System	23 Nov 2020 13:58:05
User entered 'None (0)'	System	23 Nov 2020 13:58:05

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:57:45', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '9c676010-bf93-4df2-b116-6de3e91d8953'	System	23 Nov 2020 13:58:05
User entered 'None (0)'	System	23 Nov 2020 13:58:05

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:21

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 (f1b8aa5a37a01477)', Time: '2020-11-23T08:57:52', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '9c676010-bf93-4df2-b116-6de3e91d8953'	System	23 Nov 2020 13:58:05
User entered 'No (N)'	System	23 Nov 2020 13:58:05

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:58:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '9c676010-bf93-4df2-b116-6de3e91d8953'	System	23 Nov 2020 13:58:05
User entered '23 Nov 2020 08:58'	System	23 Nov 2020 13:58:05

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 13:26:07

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 13:26:07

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 13:26:07

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 13:26:07

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 13:26:07

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 13:26:07

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 13:26:07

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 13:26:07

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 13:26:07

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 13:26:07

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '25 Nov 2022 00:01'	System	20 Nov 2020 13:26:07

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '29 Nov 2022 23:59'	System	20 Nov 2020 13:26:07

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '02 Dec 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '06 Dec 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '09 Dec 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '13 Dec 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '16 Dec 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '20 Dec 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '23 Dec 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '27 Dec 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:23:21

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:16:15

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:23
User entered 'USA-US059-2020-mRNA-1273-P301000017'	System	17 Nov 2020 13:22:19
User entered 'New'	(b) (4), (b) (6)	17 Nov 2020 13:22:19

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Emphysema, LLT: Emphysema - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 18:20:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 18:20:46
Data point term sent to Coder	System	16 Nov 2020 18:19:48
User entered 'wORSENING OF eMPHYSEMA'	Jennifer Molstead (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '09 Nov 2020'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	16 Nov 2020 18:19:44
	(b) (4)	

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Molstead (b) (4)	16 Nov 2020 18:19:44
	(b) (4)	

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	16 Nov 2020 18:19:44
	(b) (4)	

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

Severity

Audit	User	Time (GMT)
Query 'PV Query: Since the subject was hospitalized for the event of worsening of emphysema, appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 1/grade 2, please clarify/explain.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	25 Nov 2020 03:39:39
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	25 Nov 2020 03:39:29
User opened query 'PV Query: Since the subject was hospitalized for the event of worsening of emphysema, appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 1/grade 2, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:56:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jennifer Molstead (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Molstead (b) (4)	16 Nov 2020 18:19:44
	(b) (4)	

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '1'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '09 Nov 2020'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Molstead (b) (4)	16 Nov 2020 18:19:44
	(b) (4)	

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	16 Nov 2020 18:19:44
	(b) (4)	

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4)	16 Nov 2020 18:19:44
	(b) (4)	

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

[None](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Molstead (b) (4)	16 Nov 2020 18:19:44
	(b) (4)	

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: The event was reported as resolved with sequelae. Please provide the sequelae.' answered with 'this would be that she was sent home presently with oxygen' (Site from Safety).	Jennifer Molstead (b) (4)	25 Nov 2020 03:39:02
User opened query 'PV Query: The event was reported as resolved with sequelae. Please provide the sequelae.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:56:35
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Jennifer Molstead (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered 'SUBJECT WAS SENT HOME ON 2 LITERS OF CONTINUOUS OXYGEN'	Jennifer Molstead (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please report if there were any identified triggers for the worsening of the subject's emphysema.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:56:49
User opened query 'PV Query: Please provide treatment given (in addition to oxygen) for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:56:42
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:56:26
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:56:19
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:55:56
User entered 'AWAITING MEDICAL RECORDS'	Jennifer Molstead (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '0'	System	16 Nov 2020 18:19:44

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:23:21

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:16:49

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:21

[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-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:37:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:37:28
Data point term sent to Coder	System	21 Oct 2020 23:18:42
User entered 'CELEBREX'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:18:05

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:18:05

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:21

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 23:18:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 23:18:21
User entered 'LEFT KNEE ARTHRITIS' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:18:21
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 23:18:05
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:18:05

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '200'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:18:05

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:18:05

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:18:05

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:18:05

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:18:05

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:18:05

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:18:05

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:18:05

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:18:05

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:18:05

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:18:05

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 23:18:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 23:18:27
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:18:27
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 23:18:05
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:18:05

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Oct 2020 23:18:05

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 23:18:05

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 23:18:05

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 23:20:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 23:20:37
Data point term sent to Coder	System	21 Oct 2020 23:19:42
User entered 'ATORVASTATIN'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'HYPERCHOLESTERDEMIA'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2006'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: TOPIRAMATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 04:58:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 04:58:26
Data point term sent to Coder	System	21 Oct 2020 23:20:43
User entered 'TOPIRAMATE'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'SCHIZOAFFECTIVE DISORDER'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2012'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: OLANZAPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:11:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:11:23
Data point term sent to Coder	System	21 Oct 2020 23:21:47
User entered 'OLANZAPINE'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'SCHIZOAFFECTIVE DISORDER'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2016'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: OXYBUTYNIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 23:23:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 23:23:40
Data point term sent to Coder	System	21 Oct 2020 23:22:50
User entered 'OXYBUTININ'	Tammy Kohn (b) (4)	21 Oct 2020 23:22:34
	(b) (4)	

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'OVERACTIVE BLADDER'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2012'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 23:24:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 23:24:42
Data point term sent to Coder	System	21 Oct 2020 23:23:51
User entered 'LOSARTAN POTASSIUM'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'HYPERTENSION'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 23:25:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 23:25:42
Data point term sent to Coder	System	21 Oct 2020 23:24:59
User entered 'SERTRALINE'	Tammy Kohn (b) (4)	21 Oct 2020 23:24:15
	(b) (4)	

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'DEPRESSION'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2016'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 23:26:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 23:26:43
Data point term sent to Coder	System	21 Oct 2020 23:26:00
User entered 'PANTOPRAZOLE'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 07:05:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 07:05:53
Data point term sent to Coder	System	16 Nov 2020 20:19:00
User entered 'OXYGEN'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'WORSENING OF EMPHYSEMA'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '2'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'LITERS'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'CONTINUOUSLY'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:21

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

Audit	User	Time (GMT)
User entered '9 Nov 2020'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 20:18:34

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'USA-US059-2020-MRNA-1273-P301000017'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'Yes (Y)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'No (N)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'No (N)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'Yes (Y)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'No (N)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'No (N)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'No (N)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'Frank'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'Eder'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered '1290 Upper Front Street'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'Binghamton'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'NY'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered '13901'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	17 Nov 2020 13:22:46

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 13:22:46

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'USA-US059-2020-MRNA-1273-P301000017'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'Yes (Y)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'No (N)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'No (N)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'Yes (Y)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'No (N)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'No (N)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'No (N)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'Frank'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'Eder'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered '1290 Upper Front Street'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'Binghamton'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'NY'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered '13901'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	17 Nov 2020 13:22:46

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 13:22:46

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:23:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '17/Nov/2020 08:22'	System	17 Nov 2020 13:22:46

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:23:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	17 Nov 2020 13:22:46