

US3402381 (Prod: Meridian Clinical Research, LLC)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:27:39

All time stamps listed in this document are displayed in GMT

US3402381

Form: Participant Creation

Generated On: 26 Nov 2020 09:27:39

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:27:39

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	16 AUG 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 09:27:39

Date of Birth (MMM yyyy)	(b) (6) 1952
Age	67
Age Units	YEARS
Age (Derived)	67
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 09:27:39

Date of Informed Consent (<i>dd MMM yyyy</i>)	16 AUG 2020
Month and Year of Informed Consent (derived)	AUG 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 09:27:39

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:27:39

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:27:39

Condition	LATEX ALLERGY
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:27:39

Condition	CHRONIC BACK PAIN
Start date (dd MMM yyyy)	UN UNK 1989
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 1989
Start Year (derived)	1989
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:27:39

Condition	MYOCARDIAL INFARCTION
Start date (dd MMM yyyy)	03 FEB 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	03 FEB 2009
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2009
Start Year (derived)	2009
Stop Month and Year (derived)	FEB 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:27:39

Condition	ALLERGY TO GREEN PEPPERS
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:27:39

Condition	RAW MUSHROOM ALLERGY
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:27:39

Condition	BEE/WASP ALLERGY
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:27:39

Condition	CARDIAC STENT PLACEMENT
Start date (dd MMM yyyy)	03 FEB 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	03 FEB 2009
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2009
Start Year (derived)	2009
Stop Month and Year (derived)	FEB 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:27:39

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

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:27:39

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN FEB 2009
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)	FEB 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	16 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:09 (24 HR)
Vital Signs Date and Time (derived)	16 AUG 2020 12:09
Height (<i>xxx.x</i>)	184 cm
Weight (<i>xxx.x</i>)	91 kg
BMI (<i>xxx.x</i>)	26.87854 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	36.6 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	54 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:27:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:39

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

COMMUNITY ACQUIRED RISK

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) False

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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)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:27:39

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	16 AUG 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 09:27:39

What was the date of randomization? (dd MMM yyyy) 16 AUG 2020

What was the participant's randomization number? 186500

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 09:27:39

Height	184 cm
Weight	91 kg

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

Height	184 cm
Weight	91 kg
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	16 AUG 2020
Time of assessment (00:00-23:59)	12:09 (24 HR)
Vital Signs Date and Time (derived)	16 AUG 2020 12:09
Temperature (xxx.x)	36.6 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

Height	184 cm
Weight	91 kg
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	16 AUG 2020
Time of assessment (00:00-23:59)	13:39 (24 HR)
Vital Signs Date and Time (derived)	16 AUG 2020 13:39
Temperature (xxx.x)	36.0 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:27:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:27:39

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 AUG 2020

What was the treatment time? (00:00-23:59) 13:05 (24 HR)

Treatment Date and Time (derived) 16 AUG 2020 13:05

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 09:27:39

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	16 AUG 2020
Collection time (<i>00:00-23:59</i>)	12:38 (24 HR)
Collection date and time (derived)	16 AUG 2020 12:38

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:27:39

Collection date (<i>dd MMM yyyy</i>)			16 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:35	16 AUG 2020 12:35
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

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 09:27:39

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

96.9 °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

16 AUG 2020 13:43

PC Open Date & Time

16 AUG 2020 13:25

PC Close Date & Time

16 AUG 2020 15:55

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

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 96.3 °F

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

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

PC Time Stamp	16 AUG 2020 21:18
PC Open Date & Time	16 AUG 2020 16:50
PC Close Date & Time	17 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 19:26

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 20:44

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 20:53

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 20:42

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:39

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

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 22:46

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 19:39

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

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 AUG 2020 13:44

PC Open Date & Time

16 AUG 2020 13:25

PC Close Date & Time

16 AUG 2020 15:55

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

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

16 AUG 2020 21:19

PC Open Date & Time

16 AUG 2020 16:50

PC Close Date & Time

17 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:39

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 AUG 2020 19:27

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:39

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 AUG 2020 20:45

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:39

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 AUG 2020 20:54

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:39

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 AUG 2020 20:43

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:39

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 AUG 2020 22:47

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 19:40

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

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

No ☒

Yes ☐

PC Time stamp	16 AUG 2020 13:45
PC Open Date & Time	16 AUG 2020 13:25
PC Close Date & Time	16 AUG 2020 15:55

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

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

No ☒

Yes ☐

PC Time stamp	16 AUG 2020 21:20
PC Open Date & Time	16 AUG 2020 16:50
PC Close Date & Time	17 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:39

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 ☒

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:39

Yes ☐	
PC Time stamp	17 AUG 2020 19:28
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:39

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 ☒

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:39

Yes ☐	
PC Time stamp	18 AUG 2020 20:47
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:39

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 ☒

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:39

Yes ☐	
PC Time stamp	19 AUG 2020 20:55
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:39

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 ☒

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:39

Yes ☐	
PC Time stamp	20 AUG 2020 20:44
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:39

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 ☒

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:39

Yes ☐	
PC Time stamp	21 AUG 2020 22:48
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:39

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 ☒

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:39

Yes ☐	
PC Time stamp	22 AUG 2020 19:41
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3402381

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

Was Contact Attempted?

Yes ☒

No ☐

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

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402381

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402381

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402381

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402381

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402381

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402381

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:27:39

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	11:02 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 11:02
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	12:16 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 12:16
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	49 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3402381

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:27:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 SEP 2020

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

US3402381

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:27:39

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to Adverse Event ☐
	Physician withheld dose due to Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	14 SEP 2020
What was the treatment time? (00:00-23:59)	11:38 (24 HR)
Treatment Date and Time (derived)	14 SEP 2020 11:38
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3402381

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:39

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	14 SEP 2020
Collection time (<i>00:00-23:59</i>)	11:24 (24 HR)
Collection date and time (derived)	14 SEP 2020 11:24

US3402381

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:27:39

Collection date (dd MMM yyyy)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:25	14 SEP 2020 11:25
Nasopharyngeal Swab 2	No		

US3402381

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 12:17

PC Open Date & Time

14 SEP 2020 11:58

PC Close Date & Time

14 SEP 2020 14:28

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 14 SEP 2020 15:23

PC Close Date & Time 15 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 20:17

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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 SEP 2020 20:01

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 22:30

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 19:56

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:39

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

96.9 °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

19 SEP 2020 21:55

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

20 SEP 2020 21:24

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 12:18

PC Open Date & Time

14 SEP 2020 11:58

PC Close Date & Time

14 SEP 2020 14:28

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

14 SEP 2020 15:23

PC Close Date & Time

15 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:39

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

15 SEP 2020 20:18

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:39

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

16 SEP 2020 20:02

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:39

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

17 SEP 2020 22:31

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:39

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

18 SEP 2020 19:57

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:39

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

19 SEP 2020 21:56

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:39

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

20 SEP 2020 21:25

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 12:19
PC Open Date & Time	14 SEP 2020 11:58
PC Close Date & Time	14 SEP 2020 14:28

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

14 SEP 2020 15:23

PC Close Date & Time

15 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:39

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 ☒

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:39

Yes ☐	
PC Time stamp	15 SEP 2020 20:18
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:39

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 ☒

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:39

Yes ☐	
PC Time stamp	16 SEP 2020 20:03
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:39

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 ☒

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:39

Yes ☐	
PC Time stamp	17 SEP 2020 22:32
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:39

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 ☒

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:39

Yes ☐	
PC Time stamp	18 SEP 2020 19:58
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:39

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 ☒

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:39

Yes ☐	
PC Time stamp	19 SEP 2020 21:54
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:39

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 ☒

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:39

Yes ☐	
PC Time stamp	20 SEP 2020 21:25
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3402381

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402381

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402381

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402381

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402381

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402381

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402381

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:27:39

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	12 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	12 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:10 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 11:10
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402381

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:27:39

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.

US3402381

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:39

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	12 OCT 2020
Collection time (<i>00:00-23:59</i>)	11:18 (24 HR)
Collection date and time (derived)	12 OCT 2020 11:18

US3402381

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 OCT 2020 13:40:44

Patient Cloud Open Date & Time

16 OCT 2020 00:01

Patient Cloud Close Date & Time

20 OCT 2020 23:59

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 00:00:31

Patient Cloud Open Date & Time

23 OCT 2020 00:01

Patient Cloud Close Date & Time

27 OCT 2020 23:59

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 NOV 2020 08:15:21

Patient Cloud Open Date & Time

30 OCT 2020 00:01

Patient Cloud Close Date & Time

03 NOV 2020 23:59

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 NOV 2020 15:40:24
Patient Cloud Open Date & Time	13 NOV 2020 00:01
Patient Cloud Close Date & Time	17 NOV 2020 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2020 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2020 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2020 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2020 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2020 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 16:59:13
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2020 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2020 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2020 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2020 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2020 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

09 JAN 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

16 JAN 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

23 JAN 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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26 JAN 2021 00:01

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30 JAN 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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02 FEB 2021 00:01

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06 FEB 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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13 FEB 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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10 APR 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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17 APR 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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24 APR 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

01 MAY 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

08 MAY 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

15 MAY 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

22 MAY 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

29 MAY 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

05 JUN 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

12 JUN 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

19 JUN 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

26 JUN 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

03 JUL 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

10 JUL 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

17 JUL 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

24 JUL 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

31 JUL 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

07 AUG 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

14 AUG 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

21 AUG 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

28 AUG 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

04 SEP 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

11 SEP 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

18 SEP 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

25 SEP 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

02 OCT 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

09 OCT 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

16 OCT 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

23 OCT 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

30 OCT 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

06 NOV 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

13 NOV 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

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](#)

16 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

20 NOV 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

27 NOV 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

04 DEC 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

11 DEC 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

18 DEC 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

25 DEC 2021 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

01 JAN 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

08 JAN 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

15 JAN 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

22 JAN 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

29 JAN 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

05 FEB 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

12 FEB 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

19 FEB 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

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26 FEB 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

05 MAR 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

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12 MAR 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

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19 MAR 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

26 MAR 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

02 APR 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

09 APR 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

16 APR 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

23 APR 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

30 APR 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

07 MAY 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

14 MAY 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

21 MAY 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

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28 MAY 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

04 JUN 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

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11 JUN 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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14 JUN 2022 00:01

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18 JUN 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

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02 JUL 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

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16 JUL 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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06 AUG 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

Please contact your study clinic immediately. Click below to confirm that you have read this 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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13 AUG 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

20 AUG 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

27 AUG 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

03 SEP 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

10 SEP 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

17 SEP 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

24 SEP 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

01 OCT 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

08 OCT 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

15 OCT 2022 23:59

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

[Patient Cloud Close Date & Time](#)

22 OCT 2022 23:59

US3402381

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

Was Contact Attempted?

Yes ☒

No ☐

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

09 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402381

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402381

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

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

US3402381

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3402381

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:27:39

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3402381

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:27:39

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

AEID	USA-US059-2020-MRNA-1273-P30 1000015
Adverse event	PROSTATE CANCER
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)	20 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
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	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
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	True
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:	
Narrative	

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

SUBJECT WAS DIAGNOSED
WITH PROSTATE CANCER
05NOV2020 AFTER HAVING A
BIOPSY 30OCT2020. SUBJECT
BEGAN HAVING SYMPTOMS OF
BLOOD IN SPERM 20SEP2020.
SUBJECT WENT TO UROLOGIST.
AFTER BIOPSY
RESULTSSUBJECT WAS GIVRN
240 MG OF FIRMAGON SUB
CUTANEOUSLY. AND WILL GO
BACK MONTHLY FOR FURTHER
INJECTIONS OF FIRMAGON
80MG. SUBJECT WILL ALSO
BEGIN RADIATION IN
APPROXIMATELY 6 WEEKS.
THIS WAS ENTERED WITH IN 24
HOURS OF SITE AWARENESS

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)	

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:27:39

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

Yes ☒

No ☐

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

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:39

Name of Medication	LISINOPRIL
Prophylaxis	Yes ☐ No ☒
Indication	CORONARY ARTERY DISEASE
Dose per administration	2.5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:39

	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 2009
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	☒

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:39

Name of Medication	METOPROLOL
Prophylaxis	Yes ☐ No ☒
Indication	CORONARY ARTERY DISEASE
Dose per administration	25
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 ☐

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:39

	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 2009
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	☒

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:39

Name of Medication	ASPIRIN
Prophylaxis	Yes ☒ No ☐
Indication	CARDIAC PROPHYLAXIS
Dose per administration	81
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 ☐

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:39

	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 2009
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	☒

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:39

Name of Medication	ATORVASTATIN
Prophylaxis	Yes ☐ No ☒
Indication	CORONARY ARTERY 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 ☐ Intramuscular ☐

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:39

	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 2013
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	☒

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:39

Name of Medication	NAPROSYN (NAPROXEN)
Prophylaxis	Yes ☐ No ☒
Indication	CHRONIC BACK PAIN
Dose per administration	500
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:39

	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 2009
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	☒

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:39

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

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:39

	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 2015
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	☒

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:39

Name of Medication	FIRMAGON
Prophylaxis	Yes ☐ No ☒
Indication	PROSTATE CANCER
Dose per administration	240
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 ☐

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:39

	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)		05 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		05 NOV 2020
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 ☐

US3402381

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:27:39

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3402381

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 09:27:39

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

US3402381

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:27:39

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

US3402381

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:27:39

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 ☐

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

SAEID	USA-US059-2020-MRNA-1273-P301000015
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)	4

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:27:39

SAEID	USA-US059-2020-MRNA-1273-P301000015
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)	4
Date of submission (Pre-filled from custom function)	10/NOV/2020 11:55
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

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:27:39

SAEID	USA-US059-2020-MRNA-1273-P301000015
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)	4
Date of submission (Pre-filled from custom function)	19/NOV/2020 16:23
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:27:39

SAEID	USA-US059-2020-MRNA-1273-P301000015
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)	4
Date of submission (Pre-filled from custom function)	20/NOV/2020 17:52
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

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:27:39

SAEID	USA-US059-2020-MRNA-1273-P301000015
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)	4
Date of submission (Pre-filled from custom function)	23/NOV/2020 09:44
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

US3402381 (Prod: Meridian Clinical Research, LLC)

US3402381

Form: Participant Creation

Generated On: 26 Nov 2020 09:27:39

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3402381'	RWS_ENDPOINT ENDPOINT (b) (4) 	16 Aug 2020 16:24:10

US3402381

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:27:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:15:29

US3402381

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '16 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	16 Aug 2020 16:24:11

US3402381

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:15:29

US3402381

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:27:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	16 Aug 2020 17:15:29

US3402381

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:39

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered (b) (6) 1952'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	16 Aug 2020 16:24:12

US3402381

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:39

[Age](#)

Audit	User	Time (GMT)
User entered '67'	(b) (4), (b) (6)	16 Aug 2020 18:20:25

US3402381

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:39

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	16 Aug 2020 18:20:25

US3402381

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:39

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '67'	System	16 Aug 2020 17:15:40

US3402381

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:39

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	(b) (4), (b) (6)	16 Aug 2020 18:20:25

US3402381

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:39

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	16 Aug 2020 18:20:25

US3402381

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:39

[White](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	16 Aug 2020 18:20:25

US3402381

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:39

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 18:20:25

US3402381

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:39

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 18:20:25

US3402381

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:39

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 18:20:25

US3402381

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:39

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 18:20:25

US3402381

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:39

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 18:20:25

US3402381

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:39

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 18:20:25

US3402381

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:39

Unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 18:20:25

US3402381

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:39

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 18:20:25

US3402381

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '16 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:15:40

US3402381

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	16 Aug 2020 17:15:40

US3402381

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '2020'	System	16 Aug 2020 17:15:40

US3402381

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:27:39

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:15:40

US3402381

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:15:40

US3402381

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:27:39

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:15:40

US3402381

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:27:39

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:15:40

US3402381

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:27:39

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:15:40

US3402381

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:27:39

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	16 Aug 2020 16:24:11

US3402381

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:27:39

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 17:15:45

US3402381

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:15:45

US3402381

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:27:39

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 18:20:51

US3402381

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:27:39

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Rubber sensitivity, LLT: Latex allergy - version MedDRA\\23.0.	Coder Import (b) (4)	16 Aug 2020 18:22:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Aug 2020 18:22:17
Data point term sent to Coder	System	16 Aug 2020 18:21:15
User entered 'LATEX ALLERGY'	(b) (4), (b) (6)	16 Aug 2020 18:21:09

US3402381

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'UN UNK 2000'	(b) (4), (b) (6)	16 Aug 2020 18:21:09

US3402381

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:27:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 18:21:09

US3402381

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:27:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 18:21:09

US3402381

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 18:21:09

US3402381

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:27:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 18:21:09

US3402381

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	16 Aug 2020 18:21:09

US3402381

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '2000'	System	16 Aug 2020 18:21:09

US3402381

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered empty.	System	16 Aug 2020 18:21:09

US3402381

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered empty.	System	16 Aug 2020 18:21:09

US3402381

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:27:39

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 18:23:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 18:23:17
Data point term sent to Coder	System	16 Aug 2020 18:22:18
User entered 'CHRONIC BACK PAIN'	(b) (4), (b) (6)	16 Aug 2020 18:21:32

US3402381

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'UN UNK 1989'	(b) (4), (b) (6)	16 Aug 2020 18:21:32

US3402381

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:27:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 18:21:32

US3402381

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:27:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 18:21:32

US3402381

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 18:21:32

US3402381

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:27:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 18:21:32

US3402381

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Jan 1989'	System	16 Aug 2020 18:21:32

US3402381

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '1989'	System	16 Aug 2020 18:21:32

US3402381

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered empty.	System	16 Aug 2020 18:21:32

US3402381

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered empty.	System	16 Aug 2020 18:21:32

US3402381

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:27:39

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 18:23:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 18:23:17
Data point term sent to Coder	System	16 Aug 2020 18:22:20
User entered 'MYOCARDIAL INFARCTION'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Aug 2020 18:22:02

US3402381

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '03 Feb 2009'	(b) (4), (b) (6)	16 Aug 2020 18:22:02

US3402381

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:27:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 18:22:02

US3402381

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:27:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 18:22:02

US3402381

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '03 Feb 2009'	(b) (4), (b) (6)	16 Aug 2020 18:22:02

US3402381

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:27:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 18:22:02

US3402381

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Feb 2009'	System	16 Aug 2020 18:22:02

US3402381

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '2009'	System	16 Aug 2020 18:22:02

US3402381

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Feb 2009'	System	16 Aug 2020 18:22:02

US3402381

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '2009'	System	16 Aug 2020 18:22:02

US3402381

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:27:39

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Food allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 05:22:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 05:22:17
Data point term sent to Coder	System	16 Aug 2020 18:26:21
User entered 'ALLERGY TO GREEN PEPPERS'	(b) (4), (b) (6)	16 Aug 2020 18:26:03

US3402381

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'UN UNK 1980'	(b) (4), (b) (6)	16 Aug 2020 18:26:03

US3402381

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:27:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 18:26:03

US3402381

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:27:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 18:26:03

US3402381

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 18:26:03

US3402381

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:27:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 18:26:03

US3402381

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Jan 1980'	System	16 Aug 2020 18:26:03

US3402381

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '1980'	System	16 Aug 2020 18:26:03

US3402381

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered empty.	System	16 Aug 2020 18:26:03

US3402381

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered empty.	System	16 Aug 2020 18:26:03

US3402381

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:27:39

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Food allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 11:10:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 11:10:57
Data point term sent to Coder	System	16 Aug 2020 19:11:52
User entered 'RAW MUSHROOM ALLERGY'	(b) (4), (b) (6) (b) (4)	16 Aug 2020 19:10:55

US3402381

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'UN UNK 1980'	(b) (4), (b) (6)	16 Aug 2020 19:10:55

US3402381

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:27:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:10:55

US3402381

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:27:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:10:55

US3402381

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:10:55

US3402381

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:27:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:10:55

US3402381

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Jan 1980'	System	16 Aug 2020 19:10:55

US3402381

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '1980'	System	16 Aug 2020 19:10:55

US3402381

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered empty.	System	16 Aug 2020 19:10:55

US3402381

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered empty.	System	16 Aug 2020 19:10:55

US3402381

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:27:39

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Allergy to arthropod sting, LLT: Allergic reaction to bee sting - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 05:43:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 05:43:25
Data point term sent to Coder	System	16 Aug 2020 19:11:52
User entered 'BEE/WASP ALLERGY'	(b) (4), (b) (6)	16 Aug 2020 19:11:31

US3402381

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'UN UNK 1990'	(b) (4), (b) (6)	16 Aug 2020 19:11:31

US3402381

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:27:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:11:31

US3402381

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:27:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:11:31

US3402381

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:11:31

US3402381

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:27:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:11:31

US3402381

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	16 Aug 2020 19:11:31

US3402381

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '1990'	System	16 Aug 2020 19:11:31

US3402381

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered empty.	System	16 Aug 2020 19:11:31

US3402381

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered empty.	System	16 Aug 2020 19:11:31

US3402381

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:27:39

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary arterial stent insertion, LLT: Coronary stent placement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 19:13:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 19:13:25
Data point term sent to Coder	System	16 Aug 2020 19:12:52
User entered 'CARDIAC STENT PLACEMENT'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Aug 2020 19:12:11

US3402381

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '03 Feb 2009'	(b) (4), (b) (6)	16 Aug 2020 19:12:11

US3402381

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:27:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:12:11

US3402381

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:27:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:12:11

US3402381

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '03 Feb 2009'	(b) (4), (b) (6)	16 Aug 2020 19:12:11

US3402381

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:27:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:12:11

US3402381

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Feb 2009'	System	16 Aug 2020 19:12:11

US3402381

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '2009'	System	16 Aug 2020 19:12:11

US3402381

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Feb 2009'	System	16 Aug 2020 19:12:11

US3402381

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '2009'	System	16 Aug 2020 19:12:11

US3402381

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:27:39

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal signs and symptoms NEC, PT: Abdominal discomfort, LLT: Distress gastrointestinal - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 06:53:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 06:53:23
Data point term sent to Coder	System	16 Aug 2020 19:13:54
User entered 'GASTRIC DISTRESS'	(b) (4), (b) (6)	16 Aug 2020 19:13:11

US3402381

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'UN UNK 1984'	(b) (4), (b) (6)	16 Aug 2020 19:13:11

US3402381

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:27:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:13:11

US3402381

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:27:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:13:11

US3402381

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:13:11

US3402381

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:27:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:13:11

US3402381

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Jan 1984'	System	16 Aug 2020 19:13:11

US3402381

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '1984'	System	16 Aug 2020 19:13:11

US3402381

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered empty.	System	16 Aug 2020 19:13:11

US3402381

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered empty.	System	16 Aug 2020 19:13:11

US3402381

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:27:39

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 19:15:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 19:15:16
Data point term sent to Coder	System	16 Aug 2020 19:13:53
User entered 'CORONARY ARTERY DISEASE'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Aug 2020 19:13:29

US3402381

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'UN Feb 2009'	(b) (4), (b) (6)	16 Aug 2020 19:13:29

US3402381

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:27:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:13:29

US3402381

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:27:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:13:29

US3402381

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:13:29

US3402381

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:27:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:13:29

US3402381

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Feb 2009'	System	16 Aug 2020 19:13:29

US3402381

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '2009'	System	16 Aug 2020 19:13:29

US3402381

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered empty.	System	16 Aug 2020 19:13:29

US3402381

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered empty.	System	16 Aug 2020 19:13:29

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '12:09'	(b) (4), (b) (6)	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:09'	System	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '184' cm	(b) (4), (b) (6)	16 Aug 2020 19:15:09
DataPoint set to visible.	System	16 Aug 2020 17:15:45

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '91' kg	(b) (4), (b) (6)	16 Aug 2020 19:15:09
DataPoint set to visible.	System	16 Aug 2020 17:15:45

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '26.87854'	System	16 Sep 2020 23:59:08
User entered '26.9'	System	16 Aug 2020 19:15:09
DataPoint set to visible.	System	16 Aug 2020 17:15:45

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	16 Aug 2020 19:15:09
DataPoint set to visible.	System	16 Aug 2020 17:15:45

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C	(b) (4), (b) (6)	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '54'	(b) (4), (b) (6)	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '132'	(b) (4), (b) (6)	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '77'	(b) (4), (b) (6)	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Aug 2020 19:15:09

US3402381

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:27:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:15:28

US3402381

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:27:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	24 Sep 2020 10:19:11
Comment added 'PLEASE ADVISE ON RESOLUTION AS DATE IS CORRECT'.	Tammy Kohn (b) (4)	22 Sep 2020 15:17:37
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	14 Sep 2020 16:10:37
User entered '16 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 19:15:28

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:17:01

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:17:01

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:17:01

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:17:01

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:17:01

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:17:01

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:17:01

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:17:01

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:17:01

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:17:01

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:17:01

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:39

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:17:01

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:39

[Specify](#)

Audit	User	Time (GMT)
User entered 'COMMUNITY ACQUIRED RISK'	(b) (4), (b) (6)	16 Aug 2020 19:17:01

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:39

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:17:01

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:17:01

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:17:01

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:17:01

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:17:01

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	16 Aug 2020 19:17:01

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:39

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:17:01

US3402381

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:39

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:17:01

US3402381

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:27:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:18:11

US3402381

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '16 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 19:18:11

US3402381

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Aug 2020 19:18:11

US3402381

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:27:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	16 Aug 2020 19:18:11

US3402381

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '16 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	16 Aug 2020 16:24:13

US3402381

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:27:39

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:54:15
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:54:15
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Aug 2020 16:24:13
User entered '186500' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	16 Aug 2020 16:24:13

US3402381

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	16 Aug 2020 16:24:13

US3402381

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:18:31

US3402381

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:18:31

US3402381

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:18:31

US3402381

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:27:39

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:18:31

US3402381

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:27:39

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:18:31

US3402381

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User closed query 'Per CDM: This field requires yes or no. Please complete' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:08:03
Query 'Per CDM: This field requires yes or no. Please complete' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4)	03 Nov 2020 14:57:05
User entered 'No (N)'	(b) (4)	03 Nov 2020 14:56:59
User opened query 'Per CDM: This field requires yes or no. Please complete' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:33:21
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:22:18
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:33:27

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:27:39

Height

Audit	User	Time (GMT)
User entered '184' cm	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:27:39

Weight

Audit	User	Time (GMT)
User entered '91' kg	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:27:39

Height

Audit	User	Time (GMT)
User entered '184' cm	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:27:39

[Weight](#)

Audit	User	Time (GMT)
User entered '91' kg	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '12:09'	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:09'	System	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '54'	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '132'	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '77'	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:27:39

Height

Audit	User	Time (GMT)
User entered '184' cm	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:27:39

Weight

Audit	User	Time (GMT)
User entered '91' kg	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 14:29:35
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30MIN' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 19:20:42
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		16 Aug 2020 19:20:31
User entered '13:39'	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '16 Aug 2020 13:39'	System	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.0' C	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '57'	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '14'	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '117'	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '75'	(b) (4), (b) (6)	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Aug 2020 19:20:31

US3402381

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:27:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:20:50

US3402381

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:27:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 19:20:50

US3402381

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:27:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:16:06

US3402381

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:27:39

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:16:06

US3402381

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	16 Aug 2020 17:16:06
	(b) (4)	

US3402381

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:27:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	16 Aug 2020 17:16:06

US3402381

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:27:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Aug 2020'	Jennifer Molstead (b) (4)	16 Aug 2020 17:16:06
	(b) (4)	

US3402381

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '13:05'	Jennifer Molstead (b) (4)	16 Aug 2020 17:16:06
	(b) (4)	

US3402381

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '16 Aug 2020 13:05'	System	16 Aug 2020 17:16:06

US3402381

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:27:39

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Jennifer Molstead (b) (4)	16 Aug 2020 17:16:06
	(b) (4)	

US3402381

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	16 Aug 2020 17:16:06

US3402381

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:27:39

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	16 Aug 2020 17:16:06

US3402381

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:21:04

US3402381

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 19:21:04

US3402381

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '12:38'	(b) (4), (b) (6)	16 Aug 2020 19:21:04

US3402381

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:38'	System	16 Aug 2020 19:21:04

US3402381

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:27:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 19:21:33

US3402381

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:27:39

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	16 Aug 2020 19:21:33

US3402381

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:27:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:21:33

US3402381

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:27:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '12:35'	(b) (4), (b) (6)	16 Aug 2020 19:21:33

US3402381

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:35'	System	16 Aug 2020 19:21:33

US3402381

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:27:39

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	16 Aug 2020 19:21:33

US3402381

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:27:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:21:33

US3402381

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:27:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:21:33

US3402381

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered empty.	System	16 Aug 2020 19:21:33

US3402381

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:21:42

US3402381

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:21:42

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:41:42', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'd505f4c9-e908-4cb4-93d9-bf527813a75b'	System	16 Aug 2020 17:43:10
User entered 'Yes (Y)'	System	16 Aug 2020 17:43:10

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:42:26', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'd505f4c9-e908-4cb4-93d9-bf527813a75b'	System	16 Aug 2020 17:43:10
User entered '96.9'	System	16 Aug 2020 17:43:10

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:43:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'd505f4c9-e908-4cb4-93d9-bf527813a75b'	System	16 Aug 2020 17:43:10
User entered 'No (N)'	System	16 Aug 2020 17:43:10

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:43:08', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'd505f4c9-e908-4cb4-93d9-bf527813a75b'	System	16 Aug 2020 17:43:10
User entered '16 Aug 2020 13:43'	System	16 Aug 2020 17:43:10

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 13:25'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 15:55'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 1, after vaccination (at home)'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:17:39', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'a41b2cb9-1bd2-4b7c-acae-4adf0e2b4124'	System	17 Aug 2020 01:18:34
User entered 'Yes (Y)'	System	17 Aug 2020 01:18:34

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:17:55', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'a41b2cb9-1bd2-4b7c-acae-4adf0e2b4124'	System	17 Aug 2020 01:18:34
User entered '96.3'	System	17 Aug 2020 01:18:34

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:18:01', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'a41b2cb9-1bd2-4b7c-acae-4adf0e2b4124'	System	17 Aug 2020 01:18:34
User entered 'No (N)'	System	17 Aug 2020 01:18:34

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:18:29', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'a41b2cb9-1bd2-4b7c-acae-4adf0e2b4124'	System	17 Aug 2020 01:18:34
User entered '16 Aug 2020 21:18'	System	17 Aug 2020 01:18:34

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 16:50'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 2'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:25:40', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'b58237cb-dc10-4ea0-8352-bae7d58ef2ce'	System	17 Aug 2020 23:26:56
User entered 'Yes (Y)'	System	17 Aug 2020 23:26:56

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:26:04', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'b58237cb-dc10-4ea0-8352-bae7d58ef2ce'	System	17 Aug 2020 23:26:56
User entered '98.1'	System	17 Aug 2020 23:26:56

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:26:39', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'b58237cb-dc10-4ea0-8352-bae7d58ef2ce'	System	17 Aug 2020 23:26:56
User entered 'No (N)'	System	17 Aug 2020 23:26:56

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:26:51', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'b58237cb-dc10-4ea0-8352-bae7d58ef2ce'	System	17 Aug 2020 23:26:56
User entered '17 Aug 2020 19:26'	System	17 Aug 2020 23:26:56

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 3'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:44:21', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'b877f79f-74d2-489c-a288-bb5d8779d123'	System	19 Aug 2020 00:44:49
User entered 'Yes (Y)'	System	19 Aug 2020 00:44:49

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:44:32', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'b877f79f-74d2-489c-a288-bb5d8779d123'	System	19 Aug 2020 00:44:49
User entered '97.4'	System	19 Aug 2020 00:44:49

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:44:38', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'b877f79f-74d2-489c-a288-bb5d8779d123'	System	19 Aug 2020 00:44:49
User entered 'No (N)'	System	19 Aug 2020 00:44:49

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:44:45', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'b877f79f-74d2-489c-a288-bb5d8779d123'	System	19 Aug 2020 00:44:49
User entered '18 Aug 2020 20:44'	System	19 Aug 2020 00:44:49

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 4'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:53:03', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7ac94488-7b90-4a1d-800f-608e448d99d3'	System	20 Aug 2020 00:53:37
User entered 'Yes (Y)'	System	20 Aug 2020 00:53:37

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:53:11', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7ac94488-7b90-4a1d-800f-608e448d99d3'	System	20 Aug 2020 00:53:37
User entered '97.2'	System	20 Aug 2020 00:53:37

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:53:18', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7ac94488-7b90-4a1d-800f-608e448d99d3'	System	20 Aug 2020 00:53:37
User entered 'No (N)'	System	20 Aug 2020 00:53:37

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:53:32', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7ac94488-7b90-4a1d-800f-608e448d99d3'	System	20 Aug 2020 00:53:37
User entered '19 Aug 2020 20:53'	System	20 Aug 2020 00:53:37

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 5'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:42:24', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '071290ab-6832-440f-adf7-db0d88415d4c'	System	21 Aug 2020 00:42:48
User entered 'Yes (Y)'	System	21 Aug 2020 00:42:48

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:42:31', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '071290ab-6832-440f-adf7-db0d88415d4c'	System	21 Aug 2020 00:42:48
User entered '97.2'	System	21 Aug 2020 00:42:48

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:42:36', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '071290ab-6832-440f-adf7-db0d88415d4c'	System	21 Aug 2020 00:42:48
User entered 'No (N)'	System	21 Aug 2020 00:42:48

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:42:45', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '071290ab-6832-440f-adf7-db0d88415d4c'	System	21 Aug 2020 00:42:48
User entered '20 Aug 2020 20:42'	System	21 Aug 2020 00:42:48

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 6'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:46:14', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '24b79aed-d136-4b63-a110-dcdddc95b68'	System	22 Aug 2020 02:46:41
User entered 'Yes (Y)'	System	22 Aug 2020 02:46:41

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:46:25', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '24b79aed-d136-4b63-a110-dcdddc95b68'	System	22 Aug 2020 02:46:41
User entered '96.3'	System	22 Aug 2020 02:46:41

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:46:30', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '24b79aed-d136-4b63-a110-dcdddc95b68'	System	22 Aug 2020 02:46:41
User entered 'No (N)'	System	22 Aug 2020 02:46:41

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:46:38', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '24b79aed-d136-4b63-a110-dcdddc95b68'	System	22 Aug 2020 02:46:41
User entered '21 Aug 2020 22:46'	System	22 Aug 2020 02:46:41

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 7'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:39:23', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8d13136a-0a2e-4db2-9888-5dfd69251de9'	System	22 Aug 2020 23:39:48
User entered 'Yes (Y)'	System	22 Aug 2020 23:39:48

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:39:31', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8d13136a-0a2e-4db2-9888-5dfd69251de9'	System	22 Aug 2020 23:39:48
User entered '97.1'	System	22 Aug 2020 23:39:48

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:39:36', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8d13136a-0a2e-4db2-9888-5dfd69251de9'	System	22 Aug 2020 23:39:48
User entered 'No (N)'	System	22 Aug 2020 23:39:48

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:39:46', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8d13136a-0a2e-4db2-9888-5dfd69251de9'	System	22 Aug 2020 23:39:48
User entered '22 Aug 2020 19:39'	System	22 Aug 2020 23:39:48

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-08-16T13:43:49', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '3dd521d1-9216-4385-b754-8cf66bd699ee'	System	16 Aug 2020 17:44:40
User entered 'None (1)'	System	16 Aug 2020 17:44:40

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:44:05', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '3dd521d1-9216-4385-b754-8cf66bd699ee'	System	16 Aug 2020 17:44:40
User entered 'No (N)'	System	16 Aug 2020 17:44:40

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:44:17', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '3dd521d1-9216-4385-b754-8cf66bd699ee'	System	16 Aug 2020 17:44:40
User entered 'No (N)'	System	16 Aug 2020 17:44:40

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-08-16T13:44:30', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '3dd521d1-9216-4385-b754-8cf66bd699ee'	System	16 Aug 2020 17:44:40
User entered 'None (1)'	System	16 Aug 2020 17:44:40

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:44:38', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '3dd521d1-9216-4385-b754-8cf66bd699ee'	System	16 Aug 2020 17:44:40
User entered '16 Aug 2020 13:44'	System	16 Aug 2020 17:44:40

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 13:25'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 15:55'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 1, after vaccination (at home)'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-08-16T21:18:44', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1307d122-9840-49c1-a0f3-2f5fccccd82ca'	System	17 Aug 2020 01:19:32
User entered 'None (1)'	System	17 Aug 2020 01:19:32

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:18:57', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1307d122-9840-49c1-a0f3-2f5fccccd82ca'	System	17 Aug 2020 01:19:32
User entered 'No (N)'	System	17 Aug 2020 01:19:32

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:19:01', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1307d122-9840-49c1-a0f3-2f5fccccd82ca'	System	17 Aug 2020 01:19:32
User entered 'No (N)'	System	17 Aug 2020 01:19:32

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-08-16T21:19:09', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1307d122-9840-49c1-a0f3-2f5fccccd82ca'	System	17 Aug 2020 01:19:32
User entered 'None (1)'	System	17 Aug 2020 01:19:32

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:19:28', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1307d122-9840-49c1-a0f3-2f5fccccd82ca'	System	17 Aug 2020 01:19:32
User entered '16 Aug 2020 21:19'	System	17 Aug 2020 01:19:32

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 16:50'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 2'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-08-17T19:26:57', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '055d29cf-8d1e-4963-8caf-bce93af58ad0'	System	17 Aug 2020 23:27:42
User entered 'None (1)'	System	17 Aug 2020 23:27:42

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:27:01', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '055d29cf-8d1e-4963-8caf-bce93af58ad0'	System	17 Aug 2020 23:27:42
User entered 'No (N)'	System	17 Aug 2020 23:27:42

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:27:10', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '055d29cf-8d1e-4963-8caf-bce93af58ad0'	System	17 Aug 2020 23:27:42
User entered 'No (N)'	System	17 Aug 2020 23:27:42

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-08-17T19:27:16', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '055d29cf-8d1e-4963-8caf-bce93af58ad0'	System	17 Aug 2020 23:27:42
User entered 'None (1)'	System	17 Aug 2020 23:27:42

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:27:39', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '055d29cf-8d1e-4963-8caf-bce93af58ad0'	System	17 Aug 2020 23:27:42
User entered '17 Aug 2020 19:27'	System	17 Aug 2020 23:27:42

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 3'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-08-18T20:45:03', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '862d0ce4-b202-40e5-9b45-dc8bc666a47f'	System	19 Aug 2020 00:45:34
User entered 'None (1)'	System	19 Aug 2020 00:45:34

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:45:08', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '862d0ce4-b202-40e5-9b45-dc8bc666a47f'	System	19 Aug 2020 00:45:34
User entered 'No (N)'	System	19 Aug 2020 00:45:34

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:45:12', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '862d0ce4-b202-40e5-9b45-dc8bc666a47f'	System	19 Aug 2020 00:45:34
User entered 'No (N)'	System	19 Aug 2020 00:45:34

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-08-18T20:45:19', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '862d0ce4-b202-40e5-9b45-dc8bc666a47f'	System	19 Aug 2020 00:45:34
User entered 'None (1)'	System	19 Aug 2020 00:45:34

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:45:29', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '862d0ce4-b202-40e5-9b45-dc8bc666a47f'	System	19 Aug 2020 00:45:34
User entered '18 Aug 2020 20:45'	System	19 Aug 2020 00:45:34

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 4'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-08-19T20:53:39', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '5695e873-23df-4c4b-8412-64e37d31e0dc'	System	20 Aug 2020 00:54:07
User entered 'None (1)'	System	20 Aug 2020 00:54:07

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:53:43', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '5695e873-23df-4c4b-8412-64e37d31e0dc'	System	20 Aug 2020 00:54:07
User entered 'No (N)'	System	20 Aug 2020 00:54:07

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:53:53', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '5695e873-23df-4c4b-8412-64e37d31e0dc'	System	20 Aug 2020 00:54:07
User entered 'No (N)'	System	20 Aug 2020 00:54:07

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-08-19T20:53:56', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '5695e873-23df-4c4b-8412-64e37d31e0dc'	System	20 Aug 2020 00:54:07
User entered 'None (1)'	System	20 Aug 2020 00:54:07

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:54:04', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '5695e873-23df-4c4b-8412-64e37d31e0dc'	System	20 Aug 2020 00:54:07
User entered '19 Aug 2020 20:54'	System	20 Aug 2020 00:54:07

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 5'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-08-20T20:42:52', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7b301dbe-6953-4382-9557-820c86f3cc2a'	System	21 Aug 2020 00:43:21
User entered 'None (1)'	System	21 Aug 2020 00:43:21

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:42:56', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7b301dbe-6953-4382-9557-820c86f3cc2a'	System	21 Aug 2020 00:43:21
User entered 'No (N)'	System	21 Aug 2020 00:43:21

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:43:03', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7b301dbe-6953-4382-9557-820c86f3cc2a'	System	21 Aug 2020 00:43:21
User entered 'No (N)'	System	21 Aug 2020 00:43:21

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-08-20T20:43:07', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7b301dbe-6953-4382-9557-820c86f3cc2a'	System	21 Aug 2020 00:43:21
User entered 'None (1)'	System	21 Aug 2020 00:43:21

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:43:18', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7b301dbe-6953-4382-9557-820c86f3cc2a'	System	21 Aug 2020 00:43:21
User entered '20 Aug 2020 20:43'	System	21 Aug 2020 00:43:21

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 6'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-08-21T22:46:49', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0c39eb52-5b5f-4287-9c1b-2e2666b409f8'	System	22 Aug 2020 02:47:16
User entered 'None (1)'	System	22 Aug 2020 02:47:16

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:46:52', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0c39eb52-5b5f-4287-9c1b-2e2666b409f8'	System	22 Aug 2020 02:47:16
User entered 'No (N)'	System	22 Aug 2020 02:47:16

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:46:56', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0c39eb52-5b5f-4287-9c1b-2e2666b409f8'	System	22 Aug 2020 02:47:16
User entered 'No (N)'	System	22 Aug 2020 02:47:16

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-08-21T22:47:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0c39eb52-5b5f-4287-9c1b-2e2666b409f8'	System	22 Aug 2020 02:47:16
User entered 'None (1)'	System	22 Aug 2020 02:47:16

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:47:11', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0c39eb52-5b5f-4287-9c1b-2e2666b409f8'	System	22 Aug 2020 02:47:16
User entered '21 Aug 2020 22:47'	System	22 Aug 2020 02:47:16

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 7'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-08-22T19:39:56', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'f62ab1b8-616d-4cc6-a9a6-743abc339535'	System	22 Aug 2020 23:40:20
User entered 'None (1)'	System	22 Aug 2020 23:40:20

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:40:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'f62ab1b8-616d-4cc6-a9a6-743abc339535'	System	22 Aug 2020 23:40:20
User entered 'No (N)'	System	22 Aug 2020 23:40:20

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:40:03', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'f62ab1b8-616d-4cc6-a9a6-743abc339535'	System	22 Aug 2020 23:40:20
User entered 'No (N)'	System	22 Aug 2020 23:40:20

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-08-22T19:40:07', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'f62ab1b8-616d-4cc6-a9a6-743abc339535'	System	22 Aug 2020 23:40:20
User entered 'None (1)'	System	22 Aug 2020 23:40:20

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:40:17', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'f62ab1b8-616d-4cc6-a9a6-743abc339535'	System	22 Aug 2020 23:40:20
User entered '22 Aug 2020 19:40'	System	22 Aug 2020 23:40:20

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:44:47', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'f66aae69-942d-4f79-a1ce-a1b311eb8364'	System	16 Aug 2020 17:45:28
User entered 'None (0)'	System	16 Aug 2020 17:45:28

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:44:51', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'f66aae69-942d-4f79-a1ce-a1b311eb8364'	System	16 Aug 2020 17:45:28
User entered 'None (0)'	System	16 Aug 2020 17:45:28

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:44:55', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'f66aae69-942d-4f79-a1ce-a1b311eb8364'	System	16 Aug 2020 17:45:28
User entered 'None (0)'	System	16 Aug 2020 17:45:28

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:45:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'f66aae69-942d-4f79-a1ce-a1b311eb8364'	System	16 Aug 2020 17:45:28
User entered 'None (0)'	System	16 Aug 2020 17:45:28

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:45:05', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'f66aae69-942d-4f79-a1ce-a1b311eb8364'	System	16 Aug 2020 17:45:28
User entered 'None (0)'	System	16 Aug 2020 17:45:28

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:45:10', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'f66aae69-942d-4f79-a1ce-a1b311eb8364'	System	16 Aug 2020 17:45:28
User entered 'None (0)'	System	16 Aug 2020 17:45:28

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-08-16T13:45:21', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'f66aae69-942d-4f79-a1ce-a1b311eb8364'	System	16 Aug 2020 17:45:28
User entered 'No (N)'	System	16 Aug 2020 17:45:28

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T13:45:26', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'f66aae69-942d-4f79-a1ce-a1b311eb8364'	System	16 Aug 2020 17:45:28
User entered '16 Aug 2020 13:45'	System	16 Aug 2020 17:45:28

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 13:25'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 15:55'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 1, after vaccination (at home)'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:19:40', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '94b63a01-1a4b-4260-bf22-f50bbcf905ed'	System	17 Aug 2020 01:20:30
User entered 'None (0)'	System	17 Aug 2020 01:20:30

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:19:44', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '94b63a01-1a4b-4260-bf22-f50bbcf905ed'	System	17 Aug 2020 01:20:30
User entered 'None (0)'	System	17 Aug 2020 01:20:30

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:19:48', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '94b63a01-1a4b-4260-bf22-f50bbcf905ed'	System	17 Aug 2020 01:20:30
User entered 'None (0)'	System	17 Aug 2020 01:20:30

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:19:52', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '94b63a01-1a4b-4260-bf22-f50bbcf905ed'	System	17 Aug 2020 01:20:30
User entered 'None (0)'	System	17 Aug 2020 01:20:30

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:19:57', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '94b63a01-1a4b-4260-bf22-f50bbcf905ed'	System	17 Aug 2020 01:20:30
User entered 'None (0)'	System	17 Aug 2020 01:20:30

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:20:01', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '94b63a01-1a4b-4260-bf22-f50bbcf905ed'	System	17 Aug 2020 01:20:30
User entered 'None (0)'	System	17 Aug 2020 01:20:30

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-08-16T21:20:08', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '94b63a01-1a4b-4260-bf22-f50bbcf905ed'	System	17 Aug 2020 01:20:30
User entered 'No (N)'	System	17 Aug 2020 01:20:30

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-16T21:20:26', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '94b63a01-1a4b-4260-bf22-f50bbcf905ed'	System	17 Aug 2020 01:20:30
User entered '16 Aug 2020 21:20'	System	17 Aug 2020 01:20:30

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 16:50'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 2'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:27:47', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18ce3a65-d6fd-4bd9-a10d-6d82a289e864'	System	17 Aug 2020 23:29:03
User entered 'None (0)'	System	17 Aug 2020 23:29:03

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:28:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18ce3a65-d6fd-4bd9-a10d-6d82a289e864'	System	17 Aug 2020 23:29:03
User entered 'None (0)'	System	17 Aug 2020 23:29:03

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:28:04', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18ce3a65-d6fd-4bd9-a10d-6d82a289e864'	System	17 Aug 2020 23:29:03
User entered 'None (0)'	System	17 Aug 2020 23:29:03

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:28:08', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18ce3a65-d6fd-4bd9-a10d-6d82a289e864'	System	17 Aug 2020 23:29:03
User entered 'None (0)'	System	17 Aug 2020 23:29:03

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:28:29', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18ce3a65-d6fd-4bd9-a10d-6d82a289e864'	System	17 Aug 2020 23:29:03
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	17 Aug 2020 23:29:03

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:28:33', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18ce3a65-d6fd-4bd9-a10d-6d82a289e864'	System	17 Aug 2020 23:29:03
User entered 'None (0)'	System	17 Aug 2020 23:29:03

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-08-17T19:28:41', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18ce3a65-d6fd-4bd9-a10d-6d82a289e864'	System	17 Aug 2020 23:29:03
User entered 'No (N)'	System	17 Aug 2020 23:29:03

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-17T19:28:58', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18ce3a65-d6fd-4bd9-a10d-6d82a289e864'	System	17 Aug 2020 23:29:03
User entered '17 Aug 2020 19:28'	System	17 Aug 2020 23:29:03

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 3'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:45:37', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8b086e75-86af-4069-8ead-6d36eef4295f'	System	19 Aug 2020 00:48:02
User entered 'None (0)'	System	19 Aug 2020 00:48:02

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:45:40', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8b086e75-86af-4069-8ead-6d36eef4295f'	System	19 Aug 2020 00:48:02
User entered 'None (0)'	System	19 Aug 2020 00:48:02

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:45:45', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8b086e75-86af-4069-8ead-6d36eef4295f'	System	19 Aug 2020 00:48:02
User entered 'None (0)'	System	19 Aug 2020 00:48:02

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:47:02', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8b086e75-86af-4069-8ead-6d36eef4295f'	System	19 Aug 2020 00:48:02
User entered 'None (0)'	System	19 Aug 2020 00:48:02

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:47:23', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8b086e75-86af-4069-8ead-6d36eef4295f'	System	19 Aug 2020 00:48:02
User entered 'None (0)'	System	19 Aug 2020 00:48:02

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:47:27', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8b086e75-86af-4069-8ead-6d36eef4295f'	System	19 Aug 2020 00:48:02
User entered 'None (0)'	System	19 Aug 2020 00:48:02

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-08-18T20:47:35', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8b086e75-86af-4069-8ead-6d36eef4295f'	System	19 Aug 2020 00:48:02
User entered 'No (N)'	System	19 Aug 2020 00:48:02

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-18T20:47:57', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8b086e75-86af-4069-8ead-6d36eef4295f'	System	19 Aug 2020 00:48:02
User entered '18 Aug 2020 20:47'	System	19 Aug 2020 00:48:02

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 4'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:54:14', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18411b26-bee4-44a3-8e6e-857de4a11e07'	System	20 Aug 2020 00:55:09
User entered 'None (0)'	System	20 Aug 2020 00:55:09

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:54:17', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18411b26-bee4-44a3-8e6e-857de4a11e07'	System	20 Aug 2020 00:55:09
User entered 'None (0)'	System	20 Aug 2020 00:55:09

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:54:23', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18411b26-bee4-44a3-8e6e-857de4a11e07'	System	20 Aug 2020 00:55:09
User entered 'None (0)'	System	20 Aug 2020 00:55:09

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:54:29', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18411b26-bee4-44a3-8e6e-857de4a11e07'	System	20 Aug 2020 00:55:09
User entered 'None (0)'	System	20 Aug 2020 00:55:09

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:54:33', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18411b26-bee4-44a3-8e6e-857de4a11e07'	System	20 Aug 2020 00:55:09
User entered 'None (0)'	System	20 Aug 2020 00:55:09

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:54:39', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18411b26-bee4-44a3-8e6e-857de4a11e07'	System	20 Aug 2020 00:55:09
User entered 'None (0)'	System	20 Aug 2020 00:55:09

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-08-19T20:54:44', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18411b26-bee4-44a3-8e6e-857de4a11e07'	System	20 Aug 2020 00:55:09
User entered 'No (N)'	System	20 Aug 2020 00:55:09

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-19T20:55:07', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '18411b26-bee4-44a3-8e6e-857de4a11e07'	System	20 Aug 2020 00:55:09
User entered '19 Aug 2020 20:55'	System	20 Aug 2020 00:55:09

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 5'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:43:25', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '9a8ac043-2c37-435f-9655-755c0f17c0af'	System	21 Aug 2020 00:44:13
User entered 'None (0)'	System	21 Aug 2020 00:44:13

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:43:31', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '9a8ac043-2c37-435f-9655-755c0f17c0af'	System	21 Aug 2020 00:44:13
User entered 'None (0)'	System	21 Aug 2020 00:44:13

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:43:34', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '9a8ac043-2c37-435f-9655-755c0f17c0af'	System	21 Aug 2020 00:44:13
User entered 'None (0)'	System	21 Aug 2020 00:44:13

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:43:37', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '9a8ac043-2c37-435f-9655-755c0f17c0af'	System	21 Aug 2020 00:44:13
User entered 'None (0)'	System	21 Aug 2020 00:44:13

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:43:41', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '9a8ac043-2c37-435f-9655-755c0f17c0af'	System	21 Aug 2020 00:44:13
User entered 'None (0)'	System	21 Aug 2020 00:44:13

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:43:49', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '9a8ac043-2c37-435f-9655-755c0f17c0af'	System	21 Aug 2020 00:44:13
User entered 'None (0)'	System	21 Aug 2020 00:44:13

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-08-20T20:43:55', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '9a8ac043-2c37-435f-9655-755c0f17c0af'	System	21 Aug 2020 00:44:13
User entered 'No (N)'	System	21 Aug 2020 00:44:13

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-20T20:44:07', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '9a8ac043-2c37-435f-9655-755c0f17c0af'	System	21 Aug 2020 00:44:13
User entered '20 Aug 2020 20:44'	System	21 Aug 2020 00:44:13

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 6'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:47:22', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '6a6b3ee3-20a0-440f-9700-ed3c65f43b16'	System	22 Aug 2020 02:48:14
User entered 'None (0)'	System	22 Aug 2020 02:48:14

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:47:25', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '6a6b3ee3-20a0-440f-9700-ed3c65f43b16'	System	22 Aug 2020 02:48:14
User entered 'None (0)'	System	22 Aug 2020 02:48:14

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:47:29', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '6a6b3ee3-20a0-440f-9700-ed3c65f43b16'	System	22 Aug 2020 02:48:14
User entered 'None (0)'	System	22 Aug 2020 02:48:14

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:47:33', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '6a6b3ee3-20a0-440f-9700-ed3c65f43b16'	System	22 Aug 2020 02:48:14
User entered 'None (0)'	System	22 Aug 2020 02:48:14

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:47:41', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '6a6b3ee3-20a0-440f-9700-ed3c65f43b16'	System	22 Aug 2020 02:48:14
User entered 'None (0)'	System	22 Aug 2020 02:48:14

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:47:54', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '6a6b3ee3-20a0-440f-9700-ed3c65f43b16'	System	22 Aug 2020 02:48:14
User entered 'None (0)'	System	22 Aug 2020 02:48:14

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-08-21T22:48:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '6a6b3ee3-20a0-440f-9700-ed3c65f43b16'	System	22 Aug 2020 02:48:14
User entered 'No (N)'	System	22 Aug 2020 02:48:14

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-21T22:48:11', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '6a6b3ee3-20a0-440f-9700-ed3c65f43b16'	System	22 Aug 2020 02:48:14
User entered '21 Aug 2020 22:48'	System	22 Aug 2020 02:48:14

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 7'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:40:35', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '5cfe3bcb-cfd1-4fcc-a038-939b9bfd448b'	System	22 Aug 2020 23:41:33
User entered 'None (0)'	System	22 Aug 2020 23:41:33

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:40:38', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '5cfe3bcb-cfd1-4fcc-a038-939b9bfd448b'	System	22 Aug 2020 23:41:33
User entered 'None (0)'	System	22 Aug 2020 23:41:33

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:40:42', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '5cfe3bcb-cfd1-4fcc-a038-939b9bfd448b'	System	22 Aug 2020 23:41:33
User entered 'None (0)'	System	22 Aug 2020 23:41:33

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:40:46', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '5cfe3bcb-cfd1-4fcc-a038-939b9bfd448b'	System	22 Aug 2020 23:41:33
User entered 'None (0)'	System	22 Aug 2020 23:41:33

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:40:49', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '5cfe3bcb-cfd1-4fcc-a038-939b9bfd448b'	System	22 Aug 2020 23:41:33
User entered 'None (0)'	System	22 Aug 2020 23:41:33

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:40:52', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '5cfe3bcb-cfd1-4fcc-a038-939b9bfd448b'	System	22 Aug 2020 23:41:33
User entered 'None (0)'	System	22 Aug 2020 23:41:33

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-08-22T19:40:58', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '5cfe3bcb-cfd1-4fcc-a038-939b9bfd448b'	System	22 Aug 2020 23:41:33
User entered 'No (N)'	System	22 Aug 2020 23:41:33

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-08-22T19:41:31', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '5cfe3bcb-cfd1-4fcc-a038-939b9bfd448b'	System	22 Aug 2020 23:41:33
User entered '22 Aug 2020 19:41'	System	22 Aug 2020 23:41:33

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	16 Aug 2020 17:16:06

US3402381

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	24 Aug 2020 20:09:15
	(b) (4)	

US3402381

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	24 Aug 2020 20:09:15

US3402381

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Jennifer Molstead (b) (4)	24 Aug 2020 20:09:15
	(b) (4)	

US3402381

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	24 Aug 2020 20:09:15
	(b) (4)	

US3402381

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	24 Aug 2020 20:09:27
	(b) (4)	

US3402381

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 20:09:27

US3402381

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	01 Sep 2020 21:24:14

US3402381

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '1 Sep 2020'	Traci Hull (b) (4) (b) (4)	01 Sep 2020 21:24:14

US3402381

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[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)	01 Sep 2020 21:24:14

US3402381

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	01 Sep 2020 21:24:14

US3402381

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	01 Sep 2020 21:26:02

US3402381

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 21:26:02

US3402381

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	14 Sep 2020 16:10:19

US3402381

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '6 Sep 2020'	Jennifer Molstead (b) (4) (b) (4)	14 Sep 2020 16:10:19

US3402381

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Jennifer Molstead (b) (4)	14 Sep 2020 16:10:19
	(b) (4)	

US3402381

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	14 Sep 2020 16:10:19
	(b) (4)	

US3402381

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	14 Sep 2020 16:10:28

US3402381

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 16:10:28

US3402381

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:27:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	14 Sep 2020 16:10:37

US3402381

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Jennifer Molstead (b) (4) (b) (4)	14 Sep 2020 16:10:37

US3402381

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Jennifer Molstead (b) (4) (b) (4)	14 Sep 2020 16:10:37

US3402381

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:27:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	14 Sep 2020 16:10:37

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '11:02'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:02'	System	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.9' F	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '56'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '16'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '117'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '74'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '12:16'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:16'	System	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '49'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '16'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '115'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '73'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 16:35:46

US3402381

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:27:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:54

US3402381

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:27:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:35:54

US3402381

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:27:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 16:42:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 16:42:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Sep 2020 16:42:18
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 16:11:26
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	14 Sep 2020 16:11:26

US3402381

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:27:39

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	14 Sep 2020 16:11:26
	(b) (4)	

US3402381

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	14 Sep 2020 16:11:26
	(b) (4)	

US3402381

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:27:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 16:42:18
User entered empty.	System	14 Sep 2020 16:11:26

US3402381

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:27:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Jennifer Molstead (b) (4)	14 Sep 2020 16:11:26
	(b) (4)	

US3402381

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '11:38'	Jennifer Molstead (b) (4)	14 Sep 2020 16:11:26
	(b) (4)	

US3402381

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:38'	System	14 Sep 2020 16:11:26

US3402381

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:27:39

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Jennifer Molstead (b) (4)	14 Sep 2020 16:11:26
	(b) (4)	

US3402381

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	18 Sep 2020 16:42:18
User entered empty.	System	14 Sep 2020 16:11:26

US3402381

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:27:39

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 16:42:18
User entered empty.	System	14 Sep 2020 16:11:26

US3402381

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:36:17

US3402381

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:36:17

US3402381

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:24'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:36:17

US3402381

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:24'	System	14 Sep 2020 16:36:17

US3402381

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:27:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:36:29

US3402381

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:27:39

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:36:29

US3402381

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:27:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:36:29

US3402381

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:27:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '11:25'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:36:29

US3402381

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:25'	System	14 Sep 2020 16:36:29

US3402381

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:27:39

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:36:29

US3402381

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:27:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:36:29

US3402381

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:27:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:36:29

US3402381

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 16:36:29

US3402381

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 16:34:00

US3402381

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 16:34:00

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:16:51', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'a05e5187-d2bf-4539-8ce8-c6b2aa21c611'	System	14 Sep 2020 16:17:21
User entered 'Yes (Y)'	System	14 Sep 2020 16:17:21

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:17:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'a05e5187-d2bf-4539-8ce8-c6b2aa21c611'	System	14 Sep 2020 16:17:21
User entered '98.2'	System	14 Sep 2020 16:17:21

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:17:07', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'a05e5187-d2bf-4539-8ce8-c6b2aa21c611'	System	14 Sep 2020 16:17:21
User entered 'No (N)'	System	14 Sep 2020 16:17:21

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:17:16', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'a05e5187-d2bf-4539-8ce8-c6b2aa21c611'	System	14 Sep 2020 16:17:21
User entered '14 Sep 2020 12:17'	System	14 Sep 2020 16:17:21

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:58'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 14:28'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 15:23'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 2'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:17:04', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8b80edac-296d-4ba7-9870-9271c4f6eb23'	System	16 Sep 2020 00:17:31
User entered 'Yes (Y)'	System	16 Sep 2020 00:17:31

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:17:14', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8b80edac-296d-4ba7-9870-9271c4f6eb23'	System	16 Sep 2020 00:17:31
User entered '97.0'	System	16 Sep 2020 00:17:31

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:17:19', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8b80edac-296d-4ba7-9870-9271c4f6eb23'	System	16 Sep 2020 00:17:31
User entered 'No (N)'	System	16 Sep 2020 00:17:31

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:17:29', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '8b80edac-296d-4ba7-9870-9271c4f6eb23'	System	16 Sep 2020 00:17:31
User entered '15 Sep 2020 20:17'	System	16 Sep 2020 00:17:31

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 3'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:01:30', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '2a72ac71-52ef-45b0-b227-4c64e73c65a9'	System	17 Sep 2020 00:02:01
User entered 'Yes (Y)'	System	17 Sep 2020 00:02:01

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:01:39', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '2a72ac71-52ef-45b0-b227-4c64e73c65a9'	System	17 Sep 2020 00:02:01
User entered '97.0'	System	17 Sep 2020 00:02:01

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:01:45', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '2a72ac71-52ef-45b0-b227-4c64e73c65a9'	System	17 Sep 2020 00:02:01
User entered 'No (N)'	System	17 Sep 2020 00:02:01

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:01:54', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '2a72ac71-52ef-45b0-b227-4c64e73c65a9'	System	17 Sep 2020 00:02:01
User entered '16 Sep 2020 20:01'	System	17 Sep 2020 00:02:01

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 4'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:30:21', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '643ed341-416d-4d25-93e6-d219cc4f985c'	System	18 Sep 2020 02:30:46
User entered 'Yes (Y)'	System	18 Sep 2020 02:30:46

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:30:28', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '643ed341-416d-4d25-93e6-d219cc4f985c'	System	18 Sep 2020 02:30:46
User entered '97.1'	System	18 Sep 2020 02:30:46

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:30:32', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '643ed341-416d-4d25-93e6-d219cc4f985c'	System	18 Sep 2020 02:30:46
User entered 'No (N)'	System	18 Sep 2020 02:30:46

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:30:41', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '643ed341-416d-4d25-93e6-d219cc4f985c'	System	18 Sep 2020 02:30:46
User entered '17 Sep 2020 22:30'	System	18 Sep 2020 02:30:46

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 5'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:56:30', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '271944c2-9e36-4de5-a716-84844c37e684'	System	18 Sep 2020 23:56:55
User entered 'Yes (Y)'	System	18 Sep 2020 23:56:55

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:56:37', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '271944c2-9e36-4de5-a716-84844c37e684'	System	18 Sep 2020 23:56:55
User entered '97.4'	System	18 Sep 2020 23:56:55

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:56:42', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '271944c2-9e36-4de5-a716-84844c37e684'	System	18 Sep 2020 23:56:55
User entered 'No (N)'	System	18 Sep 2020 23:56:55

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:56:50', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '271944c2-9e36-4de5-a716-84844c37e684'	System	18 Sep 2020 23:56:55
User entered '18 Sep 2020 19:56'	System	18 Sep 2020 23:56:55

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 6'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:54:40', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '75d8dae3-ed9e-43e0-a578-4894d7961c1e'	System	20 Sep 2020 01:55:54
User entered 'Yes (Y)'	System	20 Sep 2020 01:55:54

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:55:01', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '75d8dae3-ed9e-43e0-a578-4894d7961c1e'	System	20 Sep 2020 01:55:54
User entered '96.9'	System	20 Sep 2020 01:55:54

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:55:05', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '75d8dae3-ed9e-43e0-a578-4894d7961c1e'	System	20 Sep 2020 01:55:54
User entered 'No (N)'	System	20 Sep 2020 01:55:54

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:55:50', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '75d8dae3-ed9e-43e0-a578-4894d7961c1e'	System	20 Sep 2020 01:55:54
User entered '19 Sep 2020 21:55'	System	20 Sep 2020 01:55:54

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 7'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:24:32', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0e0853a4-0919-476b-a73d-30fb23b75b7a'	System	21 Sep 2020 01:24:39
User entered 'Yes (Y)'	System	21 Sep 2020 01:24:39

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:24:19', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0e0853a4-0919-476b-a73d-30fb23b75b7a'	System	21 Sep 2020 01:24:39
User entered '97.7'	System	21 Sep 2020 01:24:39

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:24:23', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0e0853a4-0919-476b-a73d-30fb23b75b7a'	System	21 Sep 2020 01:24:39
User entered 'No (N)'	System	21 Sep 2020 01:24:39

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:24:37', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0e0853a4-0919-476b-a73d-30fb23b75b7a'	System	21 Sep 2020 01:24:39
User entered '20 Sep 2020 21:24'	System	21 Sep 2020 01:24:39

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-09-14T12:17:32', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '9719b86d-a775-4f6a-a08b-9211a706becc'	System	14 Sep 2020 16:18:19
User entered 'None (1)'	System	14 Sep 2020 16:18:19

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:17:52', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '9719b86d-a775-4f6a-a08b-9211a706becc'	System	14 Sep 2020 16:18:19
User entered 'No (N)'	System	14 Sep 2020 16:18:19

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:17:59', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '9719b86d-a775-4f6a-a08b-9211a706becc'	System	14 Sep 2020 16:18:19
User entered 'No (N)'	System	14 Sep 2020 16:18:19

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-09-14T12:18:07', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '9719b86d-a775-4f6a-a08b-9211a706becc'	System	14 Sep 2020 16:18:19
User entered 'None (1)'	System	14 Sep 2020 16:18:19

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:18:16', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '9719b86d-a775-4f6a-a08b-9211a706becc'	System	14 Sep 2020 16:18:19
User entered '14 Sep 2020 12:18'	System	14 Sep 2020 16:18:19

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:58'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 14:28'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 15:23'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 2'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-09-15T20:17:36', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '91fa9c40-8ea5-452d-93ea-c3d4f41ccf15'	System	16 Sep 2020 00:18:10
User entered 'None (1)'	System	16 Sep 2020 00:18:10

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:17:40', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '91fa9c40-8ea5-452d-93ea-c3d4f41ccf15'	System	16 Sep 2020 00:18:10
User entered 'No (N)'	System	16 Sep 2020 00:18:10

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:17:44', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '91fa9c40-8ea5-452d-93ea-c3d4f41ccf15'	System	16 Sep 2020 00:18:10
User entered 'No (N)'	System	16 Sep 2020 00:18:10

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-09-15T20:17:47', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '91fa9c40-8ea5-452d-93ea-c3d4f41ccf15'	System	16 Sep 2020 00:18:10
User entered 'None (1)'	System	16 Sep 2020 00:18:10

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:18:08', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '91fa9c40-8ea5-452d-93ea-c3d4f41ccf15'	System	16 Sep 2020 00:18:10
User entered '15 Sep 2020 20:18'	System	16 Sep 2020 00:18:10

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 3'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-09-16T20:02:05', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'b8fa8048-8190-459b-a13e-5ddf4c55c28c'	System	17 Sep 2020 00:02:39
User entered 'None (1)'	System	17 Sep 2020 00:02:39

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:02:09', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'b8fa8048-8190-459b-a13e-5ddf4c55c28c'	System	17 Sep 2020 00:02:39
User entered 'No (N)'	System	17 Sep 2020 00:02:39

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:02:14', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'b8fa8048-8190-459b-a13e-5ddf4c55c28c'	System	17 Sep 2020 00:02:39
User entered 'No (N)'	System	17 Sep 2020 00:02:39

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-09-16T20:02:21', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'b8fa8048-8190-459b-a13e-5ddf4c55c28c'	System	17 Sep 2020 00:02:39
User entered 'None (1)'	System	17 Sep 2020 00:02:39

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:02:32', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'b8fa8048-8190-459b-a13e-5ddf4c55c28c'	System	17 Sep 2020 00:02:39
User entered '16 Sep 2020 20:02'	System	17 Sep 2020 00:02:39

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 4'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-09-17T22:30:50', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '30ba2a8d-5d48-4e40-9ac3-0fb698df41df'	System	18 Sep 2020 02:31:33
User entered 'None (1)'	System	18 Sep 2020 02:31:33

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:31:06', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '30ba2a8d-5d48-4e40-9ac3-0fb698df41df'	System	18 Sep 2020 02:31:33
User entered 'No (N)'	System	18 Sep 2020 02:31:33

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:31:12', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '30ba2a8d-5d48-4e40-9ac3-0fb698df41df'	System	18 Sep 2020 02:31:33
User entered 'No (N)'	System	18 Sep 2020 02:31:33

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-09-17T22:31:19', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '30ba2a8d-5d48-4e40-9ac3-0fb698df41df'	System	18 Sep 2020 02:31:33
User entered 'None (1)'	System	18 Sep 2020 02:31:33

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:31:27', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '30ba2a8d-5d48-4e40-9ac3-0fb698df41df'	System	18 Sep 2020 02:31:33
User entered '17 Sep 2020 22:31'	System	18 Sep 2020 02:31:33

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 5'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-09-18T19:56:55', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'ce6f13c1-9423-4cdf-907d-f8c83def1427'	System	18 Sep 2020 23:57:25
User entered 'None (1)'	System	18 Sep 2020 23:57:25

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:56:58', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'ce6f13c1-9423-4cdf-907d-f8c83def1427'	System	18 Sep 2020 23:57:25
User entered 'No (N)'	System	18 Sep 2020 23:57:25

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:57:02', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'ce6f13c1-9423-4cdf-907d-f8c83def1427'	System	18 Sep 2020 23:57:25
User entered 'No (N)'	System	18 Sep 2020 23:57:25

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-09-18T19:57:08', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'ce6f13c1-9423-4cdf-907d-f8c83def1427'	System	18 Sep 2020 23:57:25
User entered 'None (1)'	System	18 Sep 2020 23:57:25

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:57:21', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'ce6f13c1-9423-4cdf-907d-f8c83def1427'	System	18 Sep 2020 23:57:25
User entered '18 Sep 2020 19:57'	System	18 Sep 2020 23:57:25

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 6'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-09-19T21:55:55', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7bc7cf26-0b56-4347-8a19-fa8b8040ca44'	System	20 Sep 2020 01:56:19
User entered 'None (1)'	System	20 Sep 2020 01:56:19

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:55:58', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7bc7cf26-0b56-4347-8a19-fa8b8040ca44'	System	20 Sep 2020 01:56:19
User entered 'No (N)'	System	20 Sep 2020 01:56:19

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:56:02', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7bc7cf26-0b56-4347-8a19-fa8b8040ca44'	System	20 Sep 2020 01:56:19
User entered 'No (N)'	System	20 Sep 2020 01:56:19

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-09-19T21:56:09', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7bc7cf26-0b56-4347-8a19-fa8b8040ca44'	System	20 Sep 2020 01:56:19
User entered 'None (1)'	System	20 Sep 2020 01:56:19

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:56:16', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7bc7cf26-0b56-4347-8a19-fa8b8040ca44'	System	20 Sep 2020 01:56:19
User entered '19 Sep 2020 21:56'	System	20 Sep 2020 01:56:19

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 7'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-09-20T21:24:42', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '3ab3671a-da86-49f7-80c5-699f4336161f'	System	21 Sep 2020 01:25:10
User entered 'None (1)'	System	21 Sep 2020 01:25:10

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:24:50', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '3ab3671a-da86-49f7-80c5-699f4336161f'	System	21 Sep 2020 01:25:10
User entered 'No (N)'	System	21 Sep 2020 01:25:10

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:24:53', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '3ab3671a-da86-49f7-80c5-699f4336161f'	System	21 Sep 2020 01:25:10
User entered 'No (N)'	System	21 Sep 2020 01:25:10

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-09-20T21:24:56', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '3ab3671a-da86-49f7-80c5-699f4336161f'	System	21 Sep 2020 01:25:10
User entered 'None (1)'	System	21 Sep 2020 01:25:10

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:25:06', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '3ab3671a-da86-49f7-80c5-699f4336161f'	System	21 Sep 2020 01:25:10
User entered '20 Sep 2020 21:25'	System	21 Sep 2020 01:25:10

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:18:25', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0d7c799b-17e7-4905-ba95-eb0c5100be1b'	System	14 Sep 2020 16:19:24
User entered 'None (0)'	System	14 Sep 2020 16:19:24

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:18:29', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0d7c799b-17e7-4905-ba95-eb0c5100be1b'	System	14 Sep 2020 16:19:24
User entered 'None (0)'	System	14 Sep 2020 16:19:24

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:18:32', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0d7c799b-17e7-4905-ba95-eb0c5100be1b'	System	14 Sep 2020 16:19:24
User entered 'None (0)'	System	14 Sep 2020 16:19:24

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:18:45', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0d7c799b-17e7-4905-ba95-eb0c5100be1b'	System	14 Sep 2020 16:19:24
User entered 'None (0)'	System	14 Sep 2020 16:19:24

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:18:49', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0d7c799b-17e7-4905-ba95-eb0c5100be1b'	System	14 Sep 2020 16:19:24
User entered 'None (0)'	System	14 Sep 2020 16:19:24

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:18:58', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0d7c799b-17e7-4905-ba95-eb0c5100be1b'	System	14 Sep 2020 16:19:24
User entered 'None (0)'	System	14 Sep 2020 16:19:24

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-09-14T12:19:05', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0d7c799b-17e7-4905-ba95-eb0c5100be1b'	System	14 Sep 2020 16:19:24
User entered 'No (N)'	System	14 Sep 2020 16:19:24

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-14T12:19:21', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '0d7c799b-17e7-4905-ba95-eb0c5100be1b'	System	14 Sep 2020 16:19:24
User entered '14 Sep 2020 12:19'	System	14 Sep 2020 16:19:24

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:58'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 14:28'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 15:23'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:39

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 2'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:18:15', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1fa50df4-919b-46e8-aa44-e16d753a677a'	System	16 Sep 2020 00:19:02
User entered 'None (0)'	System	16 Sep 2020 00:19:02

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:18:20', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1fa50df4-919b-46e8-aa44-e16d753a677a'	System	16 Sep 2020 00:19:02
User entered 'None (0)'	System	16 Sep 2020 00:19:02

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:18:23', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1fa50df4-919b-46e8-aa44-e16d753a677a'	System	16 Sep 2020 00:19:02
User entered 'None (0)'	System	16 Sep 2020 00:19:02

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:18:29', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1fa50df4-919b-46e8-aa44-e16d753a677a'	System	16 Sep 2020 00:19:02
User entered 'None (0)'	System	16 Sep 2020 00:19:02

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:18:35', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1fa50df4-919b-46e8-aa44-e16d753a677a'	System	16 Sep 2020 00:19:02
User entered 'None (0)'	System	16 Sep 2020 00:19:02

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:18:38', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1fa50df4-919b-46e8-aa44-e16d753a677a'	System	16 Sep 2020 00:19:02
User entered 'None (0)'	System	16 Sep 2020 00:19:02

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-09-15T20:18:47', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1fa50df4-919b-46e8-aa44-e16d753a677a'	System	16 Sep 2020 00:19:02
User entered 'No (N)'	System	16 Sep 2020 00:19:02

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-15T20:18:59', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1fa50df4-919b-46e8-aa44-e16d753a677a'	System	16 Sep 2020 00:19:02
User entered '15 Sep 2020 20:18'	System	16 Sep 2020 00:19:02

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 3'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:02:39', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '4573c5ad-fa78-4a7f-a0fe-2a072441074a'	System	17 Sep 2020 00:03:22
User entered 'None (0)'	System	17 Sep 2020 00:03:22

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:02:43', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '4573c5ad-fa78-4a7f-a0fe-2a072441074a'	System	17 Sep 2020 00:03:22
User entered 'None (0)'	System	17 Sep 2020 00:03:22

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:02:46', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '4573c5ad-fa78-4a7f-a0fe-2a072441074a'	System	17 Sep 2020 00:03:22
User entered 'None (0)'	System	17 Sep 2020 00:03:22

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:02:50', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '4573c5ad-fa78-4a7f-a0fe-2a072441074a'	System	17 Sep 2020 00:03:22
User entered 'None (0)'	System	17 Sep 2020 00:03:22

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:02:53', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '4573c5ad-fa78-4a7f-a0fe-2a072441074a'	System	17 Sep 2020 00:03:22
User entered 'None (0)'	System	17 Sep 2020 00:03:22

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:02:56', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '4573c5ad-fa78-4a7f-a0fe-2a072441074a'	System	17 Sep 2020 00:03:22
User entered 'None (0)'	System	17 Sep 2020 00:03:22

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-09-16T20:03:02', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '4573c5ad-fa78-4a7f-a0fe-2a072441074a'	System	17 Sep 2020 00:03:22
User entered 'No (N)'	System	17 Sep 2020 00:03:22

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-16T20:03:17', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '4573c5ad-fa78-4a7f-a0fe-2a072441074a'	System	17 Sep 2020 00:03:22
User entered '16 Sep 2020 20:03'	System	17 Sep 2020 00:03:22

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 4'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:31:36', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '00d9c68f-9036-4c13-b382-011bfa37b698'	System	18 Sep 2020 02:32:45
User entered 'None (0)'	System	18 Sep 2020 02:32:45

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:31:41', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '00d9c68f-9036-4c13-b382-011bfa37b698'	System	18 Sep 2020 02:32:45
User entered 'None (0)'	System	18 Sep 2020 02:32:45

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:31:47', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '00d9c68f-9036-4c13-b382-011bfa37b698'	System	18 Sep 2020 02:32:45
User entered 'None (0)'	System	18 Sep 2020 02:32:45

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:31:56', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '00d9c68f-9036-4c13-b382-011bfa37b698'	System	18 Sep 2020 02:32:45
User entered 'None (0)'	System	18 Sep 2020 02:32:45

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:32:13', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '00d9c68f-9036-4c13-b382-011bfa37b698'	System	18 Sep 2020 02:32:45
User entered 'None (0)'	System	18 Sep 2020 02:32:45

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:32:23', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '00d9c68f-9036-4c13-b382-011bfa37b698'	System	18 Sep 2020 02:32:45
User entered 'None (0)'	System	18 Sep 2020 02:32:45

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-09-17T22:32:28', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '00d9c68f-9036-4c13-b382-011bfa37b698'	System	18 Sep 2020 02:32:45
User entered 'No (N)'	System	18 Sep 2020 02:32:45

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-17T22:32:39', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '00d9c68f-9036-4c13-b382-011bfa37b698'	System	18 Sep 2020 02:32:45
User entered '17 Sep 2020 22:32'	System	18 Sep 2020 02:32:45

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 5'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:57:28', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1b9d165a-16ee-4523-b1b6-6c03ed4f912e'	System	18 Sep 2020 23:58:03
User entered 'None (0)'	System	18 Sep 2020 23:58:03

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:57:31', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1b9d165a-16ee-4523-b1b6-6c03ed4f912e'	System	18 Sep 2020 23:58:03
User entered 'None (0)'	System	18 Sep 2020 23:58:03

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:57:34', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1b9d165a-16ee-4523-b1b6-6c03ed4f912e'	System	18 Sep 2020 23:58:03
User entered 'None (0)'	System	18 Sep 2020 23:58:03

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:57:41', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1b9d165a-16ee-4523-b1b6-6c03ed4f912e'	System	18 Sep 2020 23:58:03
User entered 'None (0)'	System	18 Sep 2020 23:58:03

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:57:44', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1b9d165a-16ee-4523-b1b6-6c03ed4f912e'	System	18 Sep 2020 23:58:03
User entered 'None (0)'	System	18 Sep 2020 23:58:03

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:57:47', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1b9d165a-16ee-4523-b1b6-6c03ed4f912e'	System	18 Sep 2020 23:58:03
User entered 'None (0)'	System	18 Sep 2020 23:58:03

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-09-18T19:57:51', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1b9d165a-16ee-4523-b1b6-6c03ed4f912e'	System	18 Sep 2020 23:58:03
User entered 'No (N)'	System	18 Sep 2020 23:58:03

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-18T19:58:00', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '1b9d165a-16ee-4523-b1b6-6c03ed4f912e'	System	18 Sep 2020 23:58:03
User entered '18 Sep 2020 19:58'	System	18 Sep 2020 23:58:03

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 6'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:53:44', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'bcd36abd-6c53-4196-b414-7ccad65d986d'	System	20 Sep 2020 01:54:27
User entered 'None (0)'	System	20 Sep 2020 01:54:27

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:53:48', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'bcd36abd-6c53-4196-b414-7ccad65d986d'	System	20 Sep 2020 01:54:27
User entered 'None (0)'	System	20 Sep 2020 01:54:27

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:53:54', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'bcd36abd-6c53-4196-b414-7ccad65d986d'	System	20 Sep 2020 01:54:27
User entered 'None (0)'	System	20 Sep 2020 01:54:27

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:53:58', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'bcd36abd-6c53-4196-b414-7ccad65d986d'	System	20 Sep 2020 01:54:27
User entered 'None (0)'	System	20 Sep 2020 01:54:27

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:54:01', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'bcd36abd-6c53-4196-b414-7ccad65d986d'	System	20 Sep 2020 01:54:27
User entered 'None (0)'	System	20 Sep 2020 01:54:27

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:54:04', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'bcd36abd-6c53-4196-b414-7ccad65d986d'	System	20 Sep 2020 01:54:27
User entered 'None (0)'	System	20 Sep 2020 01:54:27

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-09-19T21:54:12', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'bcd36abd-6c53-4196-b414-7ccad65d986d'	System	20 Sep 2020 01:54:27
User entered 'No (N)'	System	20 Sep 2020 01:54:27

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-19T21:54:24', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'bcd36abd-6c53-4196-b414-7ccad65d986d'	System	20 Sep 2020 01:54:27
User entered '19 Sep 2020 21:54'	System	20 Sep 2020 01:54:27

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:11:26
User entered 'Day 7'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:39

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:25:13', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7c992764-fc17-4e37-870b-074f11431fad'	System	21 Sep 2020 01:26:00
User entered 'None (0)'	System	21 Sep 2020 01:26:00

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:39

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:25:18', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7c992764-fc17-4e37-870b-074f11431fad'	System	21 Sep 2020 01:26:00
User entered 'None (0)'	System	21 Sep 2020 01:26:00

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:25:23', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7c992764-fc17-4e37-870b-074f11431fad'	System	21 Sep 2020 01:26:00
User entered 'None (0)'	System	21 Sep 2020 01:26:00

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:25:30', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7c992764-fc17-4e37-870b-074f11431fad'	System	21 Sep 2020 01:26:00
User entered 'None (0)'	System	21 Sep 2020 01:26:00

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:25:34', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7c992764-fc17-4e37-870b-074f11431fad'	System	21 Sep 2020 01:26:00
User entered 'None (0)'	System	21 Sep 2020 01:26:00

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:39

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:25:37', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7c992764-fc17-4e37-870b-074f11431fad'	System	21 Sep 2020 01:26:00
User entered 'None (0)'	System	21 Sep 2020 01:26:00

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:39

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 (e9fe2538b25b1bad)', Time: '2020-09-20T21:25:44', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7c992764-fc17-4e37-870b-074f11431fad'	System	21 Sep 2020 01:26:00
User entered 'No (N)'	System	21 Sep 2020 01:26:00

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:39

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-09-20T21:25:55', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '7c992764-fc17-4e37-870b-074f11431fad'	System	21 Sep 2020 01:26:00
User entered '20 Sep 2020 21:25'	System	21 Sep 2020 01:26:00

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 16:11:26

US3402381

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 16:11:26

US3402381

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	21 Sep 2020 20:47:32

US3402381

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Traci Hull (b) (4) (b) (4)	21 Sep 2020 20:47:32

US3402381

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[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)	21 Sep 2020 20:47:32

US3402381

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	21 Sep 2020 20:47:32

US3402381

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	21 Sep 2020 20:47:23

US3402381

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 20:47:23

US3402381

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	29 Sep 2020 20:22:25

US3402381

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	Traci Hull (b) (4) (b) (4)	29 Sep 2020 20:22:25

US3402381

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[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)	29 Sep 2020 20:22:25

US3402381

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	29 Sep 2020 20:22:25

US3402381

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	29 Sep 2020 20:22:29

US3402381

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 20:22:29

US3402381

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	07 Oct 2020 13:29:20

US3402381

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '5 Oct 2020'	Tammy Kohn (b) (4) (b) (4)	07 Oct 2020 13:29:20

US3402381

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[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)	07 Oct 2020 13:29:20

US3402381

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	07 Oct 2020 13:29:20

US3402381

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	07 Oct 2020 13:29:24

US3402381

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 13:29:24

US3402381

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:27:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 16:15:37

US3402381

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 16:15:37

US3402381

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:27:39

[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)	12 Oct 2020 16:15:37

US3402381

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:27:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	12 Oct 2020 16:15:37

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 16:16:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 16:16:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '11:10'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 16:16:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:10'	System	12 Oct 2020 16:16:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	Traci Hull (b) (4) (b) (4)	12 Oct 2020 16:16:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 16:16:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	12 Oct 2020 16:16:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '66'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 16:16:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Oct 2020 16:16:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '16'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 16:16:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Oct 2020 16:16:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '126'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 16:16:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Oct 2020 16:16:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '78'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 16:16:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Oct 2020 16:16:07

US3402381

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:27:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 16:16:16

US3402381

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:27:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	12 Oct 2020 16:16:16

US3402381

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 16:16:32

US3402381

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 16:16:32

US3402381

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:18'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 16:16:32

US3402381

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:18'	System	12 Oct 2020 16:16:32

US3402381

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 16:15:28

US3402381

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 16:15:28

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 64'	System	16 Aug 2020 17:16:06

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-10-18T13:40:29', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '22ffa12e-0868-42d8-92ff-0782eba09f13'	System	18 Oct 2020 17:40:48
User entered 'No (N)'	System	18 Oct 2020 17:40:48

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-10-18T13:40:36', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '22ffa12e-0868-42d8-92ff-0782eba09f13'	System	18 Oct 2020 17:40:48
User entered 'No (N)'	System	18 Oct 2020 17:40:48

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-10-18T13:40:44', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '22ffa12e-0868-42d8-92ff-0782eba09f13'	System	18 Oct 2020 17:40:48
User entered '18 Oct 2020 13:40:44'	System	18 Oct 2020 17:40:48

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered '16 Oct 2020 00:01'	System	16 Aug 2020 17:16:06

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered '20 Oct 2020 23:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 71'	System	16 Aug 2020 17:16:06

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-10-25T23:59:59', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '60cbe9d3-7a27-4d0e-a6d7-dccc8ffb963e'	System	26 Oct 2020 04:00:34
User entered 'No (N)'	System	26 Oct 2020 04:00:34

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-10-26T00:00:09', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '60cbe9d3-7a27-4d0e-a6d7-dccc8ffb963e'	System	26 Oct 2020 04:00:34
User entered 'No (N)'	System	26 Oct 2020 04:00:34

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-10-26T00:00:31', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '60cbe9d3-7a27-4d0e-a6d7-dccc8ffb963e' User entered '26 Oct 2020 00:00:31'	System	26 Oct 2020 04:00:34
	System	26 Oct 2020 04:00:34

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered '23 Oct 2020 00:01'	System	16 Aug 2020 17:16:06

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered '27 Oct 2020 23:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 78'	System	16 Aug 2020 17:16:06

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-11-03T08:15:05', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '6b978ab9-b7ac-4a89-bfe7-95b8431ac11a'	System	03 Nov 2020 13:15:27
User entered 'No (N)'	System	03 Nov 2020 13:15:27

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-11-03T08:14:58', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '6b978ab9-b7ac-4a89-bfe7-95b8431ac11a'	System	03 Nov 2020 13:15:27
User entered 'No (N)'	System	03 Nov 2020 13:15:27

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-11-03T08:15:21', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '6b978ab9-b7ac-4a89-bfe7-95b8431ac11a'	System	03 Nov 2020 13:15:27
User entered '03 Nov 2020 08:15:21'	System	03 Nov 2020 13:15:27

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered '30 Oct 2020 00:01'	System	16 Aug 2020 17:16:06

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered '03 Nov 2020 23:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered 'Day 92'	System	16 Aug 2020 17:16:06

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-11-17T15:40:05', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'e3a1c205-f965-4c2b-9869-4f43fc029462'	System	17 Nov 2020 20:40:27
User entered 'No (N)'	System	17 Nov 2020 20:40:27

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-11-17T15:40:11', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'e3a1c205-f965-4c2b-9869-4f43fc029462'	System	17 Nov 2020 20:40:27
User entered 'No (N)'	System	17 Nov 2020 20:40:27

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-11-17T15:40:24', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: 'e3a1c205-f965-4c2b-9869-4f43fc029462'	System	17 Nov 2020 20:40:27
User entered '17 Nov 2020 15:40:24'	System	17 Nov 2020 20:40:27

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered '13 Nov 2020 00:01'	System	16 Aug 2020 17:16:06

US3402381

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:16:06
User entered '17 Nov 2020 23:59'	System	16 Aug 2020 17:16:06

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '13 Oct 2020 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '17 Oct 2020 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '20 Oct 2020 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '24 Oct 2020 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '27 Oct 2020 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '31 Oct 2020 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '03 Nov 2020 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '07 Nov 2020 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '10 Nov 2020 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '14 Nov 2020 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-11-21T16:58:51', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '36b2ee8e-1097-4520-9ddd-5c78e2891d0f'	System	21 Nov 2020 21:59:16
User entered 'No (N)'	System	21 Nov 2020 21:59:16

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-11-21T16:58:58', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '36b2ee8e-1097-4520-9ddd-5c78e2891d0f'	System	21 Nov 2020 21:59:16
User entered 'No (N)'	System	21 Nov 2020 21:59:16

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9fe2538b25b1bad)', Time: '2020-11-21T16:59:13', User OID: 'PatientReportedOutcome (US3402381)', ODM File OID: '36b2ee8e-1097-4520-9ddd-5c78e2891d0f' User entered '21 Nov 2020 16:59:13'	System	21 Nov 2020 21:59:16
	System	21 Nov 2020 21:59:16

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '17 Nov 2020 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '21 Nov 2020 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '24 Nov 2020 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '28 Nov 2020 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '01 Dec 2020 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '05 Dec 2020 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '08 Dec 2020 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '12 Dec 2020 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '15 Dec 2020 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '19 Dec 2020 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '22 Dec 2020 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '26 Dec 2020 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '29 Dec 2020 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '02 Jan 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '05 Jan 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '09 Jan 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '12 Jan 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '16 Jan 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '19 Jan 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '23 Jan 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '26 Jan 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '30 Jan 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '02 Feb 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '06 Feb 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '09 Feb 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '13 Feb 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '16 Feb 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '20 Feb 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '23 Feb 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '27 Feb 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '02 Mar 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '06 Mar 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '09 Mar 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '13 Mar 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '16 Mar 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '20 Mar 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '23 Mar 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '27 Mar 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '30 Mar 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '03 Apr 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '06 Apr 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '10 Apr 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '13 Apr 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '17 Apr 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '20 Apr 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '24 Apr 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '27 Apr 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '01 May 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '04 May 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '08 May 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '11 May 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '15 May 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '18 May 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '22 May 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '25 May 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '29 May 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '01 Jun 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '05 Jun 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '08 Jun 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '12 Jun 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '15 Jun 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '19 Jun 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '22 Jun 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '26 Jun 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '29 Jun 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '03 Jul 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '06 Jul 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '10 Jul 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '13 Jul 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '17 Jul 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '20 Jul 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '24 Jul 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '27 Jul 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '31 Jul 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '03 Aug 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '07 Aug 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '10 Aug 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '14 Aug 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '17 Aug 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '21 Aug 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '24 Aug 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '28 Aug 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '31 Aug 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '04 Sep 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '07 Sep 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '11 Sep 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '14 Sep 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '18 Sep 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '21 Sep 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '25 Sep 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '28 Sep 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '02 Oct 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '05 Oct 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '09 Oct 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '12 Oct 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '16 Oct 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '19 Oct 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '23 Oct 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '26 Oct 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '30 Oct 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '02 Nov 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '06 Nov 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '09 Nov 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '13 Nov 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '16 Nov 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '20 Nov 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '23 Nov 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '27 Nov 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '30 Nov 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '04 Dec 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '07 Dec 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '11 Dec 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '14 Dec 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '18 Dec 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '21 Dec 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '25 Dec 2021 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '28 Dec 2021 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '01 Jan 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '04 Jan 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '08 Jan 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '11 Jan 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '15 Jan 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '18 Jan 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '22 Jan 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '25 Jan 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '29 Jan 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '01 Feb 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '05 Feb 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '08 Feb 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '12 Feb 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '15 Feb 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '19 Feb 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '22 Feb 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '26 Feb 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '01 Mar 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '05 Mar 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '08 Mar 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '12 Mar 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '15 Mar 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '19 Mar 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '22 Mar 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '26 Mar 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '29 Mar 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '02 Apr 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '05 Apr 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '09 Apr 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '12 Apr 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '16 Apr 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '19 Apr 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '23 Apr 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '26 Apr 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '30 Apr 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '03 May 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '07 May 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '10 May 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '14 May 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '17 May 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '21 May 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '24 May 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '28 May 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '31 May 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '04 Jun 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '07 Jun 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '11 Jun 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '14 Jun 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '18 Jun 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '21 Jun 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '25 Jun 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '28 Jun 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '02 Jul 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '05 Jul 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '09 Jul 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '12 Jul 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '16 Jul 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '19 Jul 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '23 Jul 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '26 Jul 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '30 Jul 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '02 Aug 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '06 Aug 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '09 Aug 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '13 Aug 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '16 Aug 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '20 Aug 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '23 Aug 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '27 Aug 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '30 Aug 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '03 Sep 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '06 Sep 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '10 Sep 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '13 Sep 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '17 Sep 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '20 Sep 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '24 Sep 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '27 Sep 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '01 Oct 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '04 Oct 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '08 Oct 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '11 Oct 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '15 Oct 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '18 Oct 2022 00:01'	System	19 Nov 2020 08:46:14

US3402381

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:14
Amendment Manager: User entered '22 Oct 2022 23:59'	System	19 Nov 2020 08:46:14

US3402381

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:31:22
	(b) (4)	

US3402381

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '09 Nov 2020'	Jennifer Molstead (b) (4)	09 Nov 2020 15:31:22
	(b) (4)	

US3402381

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:31:22
	(b) (4)	

US3402381

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	09 Nov 2020 15:31:22
	(b) (4)	

US3402381

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:31:28
	(b) (4)	

US3402381

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 15:31:28

US3402381

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:27:39

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:59:41
User entered 'Yes (Y)' reason for change: New Information	Jennifer Molstead (b) (4)	09 Nov 2020 15:31:45
User entered 'No (N)'	Traci Hull (b) (4)	10 Sep 2020 13:06:17
	(b) (4)	

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:47:03
User entered 'USA-US059-2020-mRNA-1273-P301000015'	System	10 Nov 2020 16:46:57
User entered 'New'	(b) (4), (b) (6)	10 Nov 2020 16:46:57

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 15:42:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 15:42:34
	(b) (4)	
Data point term sent to Coder	System	09 Nov 2020 15:41:35
User entered 'Prostate Cancer'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23
	(b) (4)	

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23
	(b) (4)	

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered 'No (N)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23
	(b) (4)	

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered 'No (N)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23
	(b) (4)	

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered '20 Sep 2020'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23
	(b) (4)	

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered empty.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23
	(b) (4)	

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 15:41:23

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23
	(b) (4)	

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 23:07:06
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'their is no end date to provide as patient is undergoing radiation for the next 6 weeks' (Site from Safety).	Tammy Kohn (b) (4)	23 Nov 2020 16:07:13
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 16:02:46
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	10 Nov 2020 00:12:22
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	10 Nov 2020 00:12:22
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	10 Nov 2020 00:11:40
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	10 Nov 2020 00:11:06
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	10 Nov 2020 00:11:06
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	10 Nov 2020 00:10:41
User entered empty.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered empty.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23
	(b) (4)	

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 15:41:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23
	(b) (4)	

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23
	(b) (4)	

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered '0'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered '0'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23
	(b) (4)	

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered '0'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered empty.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23
	(b) (4)	

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered empty.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23
	(b) (4)	

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered empty.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered empty.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23
	(b) (4)	

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered '0'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23
	(b) (4)	

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered '0'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23
	(b) (4)	

US3402381

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered '1'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 06:31:05
Query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related.' canceled (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 16:04:06
User opened query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 16:03:49
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	18 Nov 2020 13:44:14
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Nov 2020 13:44:05
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:22:10
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Molstead (b) (4) (b) (4)	09 Nov 2020 15:41:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User closed query 'Per CDM re-query: Thank you for updating Relationship to IP as Not related as per previous query. However there is no update made for this field. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 05:10:12
User closed query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 23:07:24
Query 'Per CDM re-query: Thank you for updating Relationship to IP as Not related as per previous query. However there is no update made for this field. Please review and update as appropriate. Thank you' answered with 'updated to Not Related ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Nov 2020 16:05:37
User entered 'Not Related (NOT RELATED)' reason for change: Per Query Resolution	Tammy Kohn (b) (4) (b) (4)	23 Nov 2020 16:04:27
User opened query 'Per CDM re-query: Thank you for updating Relationship to IP as Not related as per previous query. However there is no update made for this field. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 04:13:27
Query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	20 Nov 2020 21:14:02
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	20 Nov 2020 21:13:52
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 17:22:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 17:22:23
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	19 Nov 2020 17:22:23
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 17:22:07
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	19 Nov 2020 17:22:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 16:06:33
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered '0'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered '1'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered '1'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 23:07:33
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'at this point this in not expected to resolve' (Site from Safety).	Jennifer Molstead (b) (4)	23 Nov 2020 21:11:44
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 16:03:13
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	10 Nov 2020 00:22:50
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	10 Nov 2020 00:12:22
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	10 Nov 2020 00:12:22
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	10 Nov 2020 00:12:22
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	10 Nov 2020 00:11:40
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	10 Nov 2020 00:11:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	10 Nov 2020 00:11:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	10 Nov 2020 00:11:06
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	10 Nov 2020 00:11:06
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	10 Nov 2020 00:10:41
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	10 Nov 2020 00:10:41
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	09 Nov 2020 15:41:23
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered empty; reason for change Per Query Resolution	Jennifer Molstead (b) (4)	10 Nov 2020 00:22:50
User entered 'Subject was diagnosed with Prostate cancer 05Nov2020 after having a biopsy 30Oct2020. Subject began having symptoms of blood in sperm 20Sep2020. Subject went to Urologist. After Biopsy results'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:36
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:32
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:54:28
User entered 'SUBJECT WAS DIAGNOSED WITH PROSTATE CANCER 05NOV2020 AFTER HAVING A BIOPSY 30OCT2020. SUBJECT BEGAN HAVING SYMPTOMS OF BLOOD IN SPERM 20SEP2020. SUBJECT WENT TO UROLOGIST. AFTER BIOPSY RESULTSSUBJECT WAS GIVRN 240 MG OF FIRMAGON SUB CUTANEOUSLY. AND WILL GO BACK MONTHLY FOR FURTHER INJECTIONS OF FIRMAGON 80MG. SUBJECT WILL ALSO BEGIN RADIATION IN APPROXIMATELY 6 WEEKS. This was entered with in 24 hours of site awareness' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	20 Nov 2020 21:12:02
User entered 'SUBJECT WAS DIAGNOSED WITH PROSTATE CANCER 05NOV2020 AFTER HAVING A BIOPSY 30OCT2020. SUBJECT BEGAN HAVING SYMPTOMS OF BLOOD IN SPERM 20SEP2020. SUBJECT WENT TO UROLOGIST. AFTER BIOPSY RESULTSSUBJECT WAS GIVRN 240 MG OF FIRMAGON SUB CUTANEOUSLY. AND WILL GO BACK MONTHLY FOR FURTHER INJECTIONS OF FIRMAGON 80MG. SUBJECT WILL ALSO BEGIN RADIATION IN APPROXIMATELY 6 WEEKS.' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	10 Nov 2020 00:22:50
User entered 'Subject was givrn 240 mg of Firmagon Sub cutaneously. And will go back monthly for further injections of Firmagon 80mg. Subject will also begin radiation in approximately 6 weeks.'	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 15:41:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 15:41:23

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:27:39

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:59:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:22:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 19:24:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 19:24:16
Data point term sent to Coder	System	16 Aug 2020 19:24:00
User entered 'LISINOPRIL'	(b) (4), (b) (6)	16 Aug 2020 19:23:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:23:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'CORONARY ARTERY DISEASE'	(b) (4), (b) (6)	16 Aug 2020 19:23:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '2.5'	(b) (4), (b) (6)	16 Aug 2020 19:23:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Aug 2020 19:23:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:23:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'once daily (QD)'	(b) (4), (b) (6)	16 Aug 2020 19:23:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:23:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Aug 2020 19:23:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:23:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 17:53:33
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	16 Aug 2020 19:31:41
answered with 'ONGOING' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	16 Aug 2020 19:23:12
User entered 'UN UNK 2009'	(b) (4), (b) (6)	16 Aug 2020 19:23:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:23:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:23:12

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:23:12

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:23:12

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:23:12

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:23:12

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Aug 2020 19:23:12

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 19:24:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 19:24:16
Data point term sent to Coder	System	16 Aug 2020 19:24:00
User entered 'METOPROLOL'	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'CORONARY ARTERY DISEASE'	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '25'	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'twice daily (BID)'	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 18:22:40
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	16 Aug 2020 19:31:48
answered with 'ONGOING' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	16 Aug 2020 19:24:00
User entered 'UN UNK 2009'	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Aug 2020 19:24:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Aug 2020 19:26:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Aug 2020 19:26:16
Data point term sent to Coder	System	16 Aug 2020 19:25:01
User entered 'ASPIRIN'	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'CARDIAC PROPHYLAXIS'	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '81'	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'once daily (QD)'	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 18:22:48
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	16 Aug 2020 19:31:54
answered with 'ONGOING' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	16 Aug 2020 19:24:32
User entered 'UN UNK 2009'	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Aug 2020 19:24:32

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
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)	16 Aug 2020 19:27:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 19:27:16
Data point term sent to Coder	System	16 Aug 2020 19:26:01
User entered 'ATORVASTATIN'	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'CORONARY ARTERY DISEASE'	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '40'	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'once daily (QD)'	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 18:22:54
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	16 Aug 2020 19:32:00
answered with 'ONGOING' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	16 Aug 2020 19:25:08
User entered 'UN UNK 2013'	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Aug 2020 19:25:08

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN, PRODUCTSYNONYM: NAPROSYN [NAPROXEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 06:50:21
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 Aug 2020 06:50:21
Data point term sent to Coder	System	16 Aug 2020 19:26:01
User entered 'NAPROSYN (NAPROXEN)'	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'CHRONIC BACK PAIN'	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '500'	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'once daily (QD)'	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 18:23:00
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	16 Aug 2020 19:32:05
answered with 'ONGOING' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	16 Aug 2020 19:25:47
User entered 'UN UNK 2009'	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Aug 2020 19:25:47

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 06:43:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 06:43:29
Data point term sent to Coder	System	16 Aug 2020 19:28:02
User entered 'PROBIOTIC'	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'DIGESTIVE DISTRESS'	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '2'	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'capsule (CAPSULE)'	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'once daily (QD)'	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 18:29:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	16 Aug 2020 19:32:11
answered with 'ONGOING' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	16 Aug 2020 19:28:00
User entered 'UN UNK 2015'	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Aug 2020 19:28:00

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONE ANTAGONISTS AND RELATED AGENTS, ATC: OTHER HORMONE ANTAGONISTS AND RELATED AGENTS, PRODUCT: DEGARELIX ACETATE, PRODUCTSYNONYM: FIRMAGON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 15:58:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 15:58:33
Data point term sent to Coder	System	09 Nov 2020 15:42:38
User entered 'Firmagon'	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'No (N)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Prostate Cancer'	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '240'	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'once (ONCE)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:39

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered empty.	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '05 Nov 2020'	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '0'	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'No (N)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered '05 Nov 2020'	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:02
User entered 'No (N)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:30
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 15:42:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 15:42:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 15:42:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	09 Nov 2020 15:41:41
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	(b) (4), (b) (6)	16 Aug 2020 19:31:35

US3402381

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:27:39

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:10
User entered 'Yes (Y)' reason for change: New Information	Jennifer Molstead (b) (4)	09 Nov 2020 15:42:41
User entered 'No (N)'	Traci Hull (b) (4)	10 Sep 2020 13:06:23
	(b) (4)	

US3402381

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:27:39

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:25
User entered '30 Oct 2020'	Jennifer Molstead (b) (4)	09 Nov 2020 15:43:02
	(b) (4)	

US3402381

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:27:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:25
User entered 'Prostate Biopsy'	Jennifer Molstead (b) (4)	09 Nov 2020 15:43:02
	(b) (4)	

US3402381

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:27:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:25
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4)	09 Nov 2020 15:43:02
	(b) (4)	

US3402381

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:27:39

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:03:25
User entered empty.	Jennifer Molstead (b) (4)	09 Nov 2020 15:43:02
	(b) (4)	

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'USA-US059-2020-MRNA-1273-P301000015'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Yes (Y)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

Death

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Yes (Y)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Frank'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Eder'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered '1290 Upper Front Street'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Binghamton'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'NY'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered '13901'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:23:24
User entered 'US'	System	10 Nov 2020 16:55:51

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Nov 2020 14:44:56
User entered '3'	System	20 Nov 2020 17:52:09
User entered '2'	System	19 Nov 2020 16:23:41
User entered '1'	System	10 Nov 2020 16:55:51

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'USA-US059-2020-MRNA-1273-P301000015'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Yes (Y)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

Death

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Yes (Y)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Frank'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Eder'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered '1290 Upper Front Street'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Binghamton'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'NY'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered '13901'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:23:24
User entered 'US'	System	10 Nov 2020 16:55:51

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Nov 2020 14:44:56
User entered '3'	System	20 Nov 2020 17:52:09
User entered '2'	System	19 Nov 2020 16:23:41
User entered '1'	System	10 Nov 2020 16:55:51

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:27:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '10/Nov/2020 11:55'	System	10 Nov 2020 16:55:51

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:27:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:23:24
User entered '1'	(b) (4), (b) (6)	10 Nov 2020 16:55:51

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'USA-US059-2020-MRNA-1273-P301000015'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Yes (Y)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

Death

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Yes (Y)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Frank'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Eder'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered '1290 Upper Front Street'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Binghamton'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'NY'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered '13901'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:23:24
User entered 'US'	System	10 Nov 2020 16:55:51

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Nov 2020 14:44:56
User entered '3'	System	20 Nov 2020 17:52:09
User entered '2'	System	19 Nov 2020 16:23:41
User entered '1'	System	10 Nov 2020 16:55:51

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:27:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '19/Nov/2020 16:23'	System	19 Nov 2020 16:23:41

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:27:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 17:52:00
User entered '1'	(b) (4), (b) (6)	19 Nov 2020 16:23:41

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'USA-US059-2020-MRNA-1273-P301000015'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Yes (Y)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Yes (Y)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Frank'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Eder'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered '1290 Upper Front Street'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Binghamton'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'NY'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered '13901'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:23:24
User entered 'US'	System	10 Nov 2020 16:55:51

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Nov 2020 14:44:56
User entered '3'	System	20 Nov 2020 17:52:09
User entered '2'	System	19 Nov 2020 16:23:41
User entered '1'	System	10 Nov 2020 16:55:51

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:27:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '20/Nov/2020 17:52'	System	20 Nov 2020 17:52:09

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:27:39

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)	20 Nov 2020 17:52:09

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'USA-US059-2020-MRNA-1273-P301000015'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Yes (Y)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'No (N)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Yes (Y)'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Frank'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Eder'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered '1290 Upper Front Street'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'Binghamton'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered 'NY'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
User entered '13901'	System	10 Nov 2020 16:46:57

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:23:24
User entered 'US'	System	10 Nov 2020 16:55:51

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Nov 2020 14:44:56
User entered '3'	System	20 Nov 2020 17:52:09
User entered '2'	System	19 Nov 2020 16:23:41
User entered '1'	System	10 Nov 2020 16:55:51

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:27:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '23/Nov/2020 09:44'	System	23 Nov 2020 14:44:56

US3402381

Folder: SAE USA-US059-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:27:39

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)	23 Nov 2020 14:44:56